Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (Text with EEA relevance)

## ANNEX I

# **DEFINITIONS AS REFERRED TO IN ARTICLE 2**

For the purpose of this Regulation, the following definitions shall apply:

- 1. **'fur animals**' means animals kept or reared for the production of fur and not used for human consumption;
- 2. **'blood**' means fresh whole blood;
- 3. **'feed material**' means those feed materials, as defined in Article 3(2)(g) of Regulation (EC) No 767/2009, that are of animal origin, including processed animal proteins, blood products, rendered fats, egg products, fish oil, fat derivatives, collagen, gelatine and hydrolysed proteins, dicalcium phosphate, tricalcium phosphate, milk, milk-based products, milk-derived products, colostrum, colostrum products and centrifuge or separator sludge;
- 4. **'blood products'** means derived products from blood or fractions of blood, excluding blood meal; they include dried/frozen/liquid plasma, dried whole blood, dried/frozen/liquid red cells or fractions thereof and mixtures;
- 5. **'processed animal protein**' means animal protein derived entirely from Category 3 material, which have been treated in accordance with Section 1 of Chapter II of Annex X (including blood meal and fishmeal) so as to render them suitable for direct use as feed material or for any other use in feedingstuffs, including petfood, or for use in organic fertilisers or soil improvers; however, it does not include blood products, milk, milk-based products, milk-derived products, colostrum, colostrum products, centrifuge or separator sludge, gelatine, hydrolysed proteins and dicalcium phosphate, eggs and egg-products, including eggshells, tricalcium phosphate and collagen;
- 6. **'blood meal'** means processed animal protein derived from the heat treatment of blood or fractions of blood in accordance with Section 1 of Chapter II of Annex X;
- 7. **'fishmeal'** means processed animal protein derived from aquatic animals, except sea mammals;
- 8. **'rendered fats'** means either fats derived from the processing of:
  - (a) animal by-products; or
  - (b) products for human consumption, which an operator has destined for purposes other than human consumption;
- 9. **'fish oil'** means oil derived from the processing of aquatic animals or oil from the processing of fish for human consumption, which an operator has destined for purposes other than human consumption;
- 10. **'apiculture by-products**' means honey, beeswax, royal jelly, propolis or pollen not intended for human consumption;
- 11. **'collagen'** means protein-based products derived from hides, skins, bones and tendons of animals;
- 12. **'gelatine'** means natural, soluble protein, gelling or non-gelling, obtained by the partial hydrolysis of collagen produced from bones, hides and skins, tendons and sinews of animals;

- 13. **'greaves'** means the protein-containing residue of rendering, after partial separation of fat and water;
- 14. **'hydrolysed proteins'** means polypeptides, peptides and aminoacids, and mixtures thereof, obtained by the hydrolysis of animal by-products;
- 15. **'white water'** means a mixture of milk, milk-based products or products derived thereof with water which is collected during the rinsing of dairy equipment including containers used for dairy products, prior to their cleaning and disinfection;
- 16. **'canned petfood'** means heat-processed petfood contained within a hermetically sealed container;
- 17. **'dogchews'** means products for pet animals to chew, produced from untanned hides and skins of ungulates or from other material of animal origin;
- 18. **'flavouring innards'** means a liquid or dehydrated derived product of animal origin used to enhance the palatability values of petfood;
- 19. '[<sup>F1</sup>**petfood**' means feed, other than material referred to in Article 24(2), for use as feed for pet animals, and dogchews consisting of animal by-products or derived products which:
  - (a) contain Category 3 material, other than material referred to in Article 10(n),
     (o) and (p) of Regulation (EC) No 1069/2009; and
  - (b) may contain imported Category 1 material comprising of animal by-products derived from animals which have been submitted to illegal treatment as defined in Article 1(2)(d) of Directive 96/22/EC or Article 2(b) of Directive 96/23/EC;]
- 20. **'processed petfood**' means petfood, other than raw petfood, which has been processed in accordance with point 3 of Chapter II of Annex XIII;
- 21. **'raw petfood**' means petfood containing certain Category 3 material which has not undergone any preserving process other than chilling or freezing;
- 22. **'catering waste'** means all waste food, including used cooking oil originating in restaurants, catering facilities and kitchens, including central kitchens and household kitchens;
- 23. '[<sup>F1</sup>digestion residues' means residues, including the liquid fraction, resulting from the transformation of animal by-products in a biogas plant;]
- 24. **'digestive tract content**' means the content of the digestive tract of mammals and ratites;
- 25. **'fat derivatives'** means derived products from rendered fats, which, as regards rendered fats of Category 1 or Category 2 material, have been processed in accordance with Chapter XI of Annex XIII;
- 26. **'guano'** means a natural product which has been collected from the excrements of bats or wild sea birds and which is not mineralised;
- 27. **'meat-and-bone meal**' means animal protein derived from the processing of Category 1 or Category 2 materials in accordance with one of the processing methods set out in Chapter III of Annex IV;

- 28. **'treated hides and skins**' means derived products from untreated hides and skins, other than dogchews, that have been:
  - (a) dried;
  - (b) dry-salted or wet-salted for a period of at least 14 days prior to dispatch;
  - (c) salted for a period of at least seven days in sea salt with the addition of 2 % of sodium carbonate;
  - (d) dried for a period of at least 42 days at a temperature of at least 20 °C; or
  - (e) subject to a preservation process other than tanning;
- 29. **'untreated hides and skins'** means all cutaneous and subcutaneous tissues that have not undergone any treatment, other than cutting, chilling or freezing;
- 30. **'untreated feathers and parts of feathers**' means feathers and parts of feathers, other than feathers or parts of feathers, which have been treated:
  - (a) with a steam current; or
  - (b) by another method that ensures that no unacceptable risks remain;
- 31. (<sup>F2</sup>untreated wool' means wool, other than wool which has:
  - (a) undergone factory washing;
  - (b) been obtained from tanning;
  - (c) been treated by another method that ensures that no unacceptable risks remain;
  - (d) been produced from animals other than those of the porcine species, and has undergone factory-washing which consisting of the immersion of the wool in series of baths of water, soap and sodium hydroxide or potassium hydroxide; or
  - (e) been produced from animals other than those of the porcine species, is intended for being dispatched directly to a plant producing derived products from wool for the textile industry and has undergone at least one of the following treatments:
    - (i) chemical depilation by means of slaked lime or sodium sulphide;
    - (ii) fumigation in formaldehyde in a hermetically sealed chamber for at least 24 hours;
    - (iii) industrial scouring which consists of the immersion of wool in a water-soluble detergent held at 60–70 °C;
    - (iv) storage, which may include the journey time, at 37 °C for eight days, 18 °C for 28 days or 4 °C for 120 days;
- 32. **'untreated hair**' means hair, other than hair which has:
  - (a) undergone factory washing;
  - (b) been obtained from tanning;

- (c) been treated by another method that ensures that no unacceptable risks remain;
- (d) been produced from animals other than those of the porcine species, and has undergone factory-washing which consisting of the immersion of the hair in series of baths of water, soap and sodium hydroxide or potassium hydroxide; or
- (e) been produced from animals other than those of the porcine species, is intended for being dispatched directly to a plant producing derived products from hair for the textile industry and has undergone at least one of the following treatments:
  - (i) chemical depilation by means of slaked lime or sodium sulphide;
  - (ii) fumigation in formaldehyde in a hermetically sealed chamber for at least 24 hours;
  - (iii) industrial scouring which consists of the immersion of hair in a water-soluble detergent held at 60-70 °C;
  - (iv) storage, which may include the journey time, at 37 °C for eight days, 18 °C for 28 days or 4 °C for 120 days;]
- 33. **'untreated pig bristles**' means pig bristles, other than pig bristles which have:
  - (a) undergone factory washing;
  - (b) been obtained from tanning; or
  - (c) been treated by another method that ensures that no unacceptable risks remain;
- 34. **'display item'** means animal by-products or derived products intended for exhibitions or artistic activities;
- 35. ([<sup>F3</sup>intermediate product' means a derived product:
  - (a) which is intended for uses within the manufacturing of medicinal products, veterinary medicinal products, medical devices for medical and veterinary purposes, active implantable medical devices, *in vitro* diagnostic medical devices for medical and veterinary purposes, laboratory reagents or cosmetic products as follows:
    - (i) as material in a manufacturing process or in the final production of a finished product;
    - (ii) in validation or verification during a manufacturing process; or
    - (iii) in quality control of a finished product;
  - (b) whose design, transformation and manufacturing stages have been sufficiently completed in order to be regarded as a derived product and to qualify the material directly or as a component of a product for the purposes referred to in point (a);
  - (c) which however requires some further manufacturing or transformation, such as mixing, coating, assembling or packaging to make it suitable for placing

on the market or putting into service, as applicable, a medicinal product, veterinary medicinal product, medical device for medical and veterinary purposes, active implantable medical device, *in vitro* diagnostic medical devices for medical and veterinary purposes, laboratory reagent or cosmetic products;]

- 36. **'laboratory reagent'** means a packaged product, ready for use, containing animal byproducts or derived products and intended as such or in combination with substances of non-animal origin for specific laboratory use as a reagent or reagent product, calibrator or control material to detect, measure, examine or produce other substances;
- 37. **'product used for in vitro diagnosis'** means a packaged product, ready for use, containing a blood product or another animal by-product, and used as a reagent, reagent product, calibrator, kit or any other system, whether used alone or in combination, intended to be used in vitro for the examination of samples of human or animal origin, solely or principally with a view to the diagnosis of a physiological state, state of health, disease or genetic abnormality or to determine safety and compatibility with reagents; it does not include donated organs or blood;
- 38. **'research and diagnostic samples'** means animal by-products and derived products intended for the following purposes: examination in the context of diagnostic activities or analysis for the promotion of progress in science and technology, in the context of educational or research activities;
- 39. '[<sup>F3</sup>trade samples' means animal by-products or derived products intended for particular studies or analyses authorised by the competent authority in accordance with Article 17(1) of Regulation (EC) No 1069/2009 with a view to carrying out a production process, including the processing of animal by-products or derived products, the development of feedingstuff, pet food or derived products, or the testing of machinery or equipment;]
- 40. **'co-incineration'** means the recovery or disposal of animal by-products or derived products, if they are waste, in a co-incineration plant;
- 41. **'combustion**' means a process involving the oxidisation of fuel in order to use the energy value of the animal by-products or derived products, if they are not waste;
- 42. **'incineration**' means the disposal of animal by-products or derived products as waste, in an incineration plant, as defined in point 4 of Article 3 of Directive 2000/76/EC;
- 43. **'incineration and co-incineration residues**' means any residues as defined in point 13 of Article 3 of Directive 2000/76/EC, which are generated by incineration or co-incineration plants treating animal by-products or derived products;
- 44. **'colour-coding'** means the systematic use of colours as set out in point 1(c) of Chapter II of Annex VIII for displaying information as provided for in this Regulation on the surface or on part of the surface of a packaging, container or vehicle, or on a label or symbol applied to them;
- 45. **'intermediate operations'** means the operations, other than storage, referred to in Article 19(b);
- 46. **'tanning'** means the hardening of hides, using vegetable tanning agents, chromium salts or other substances such as aluminium salts, ferric salts, silicic salts, aldehydes and quinones, or other synthetic hardening agents;

- 47. **'taxidermy'** means the art of preparing, stuffing and mounting the skins of animals with lifelike effect, so that no unacceptable risks to public and animal health may be transmitted through the mounted skin;
- 48. **'trade'** means trade in goods between Member States as referred to in Article 28 of the Treaty on the Functioning of the European Union;
- 49. **'processing methods**' means the methods listed in Chapters III and IV of Annex IV;
- 50. **'batch'** means a unit of production produced in a single plant using uniform production parameters, such as the origin of the materials, or a number of such units, when produced in continuous order in a single plant and stored together as a shipping unit;
- 51. **'hermetically sealed container'** means a container that is designed and intended to be secure against the entry of micro-organisms;
- 52. **'biogas plant**' means a plant in which animal by-products or derived products are at least part of the material which is submitted to biological degradation under anaerobic conditions;
- 53. **'collection centres'** means premises other than processing plants in which the animal by-products referred to in Article 18(1) of Regulation (EC) No 1069/2009 are collected with the intention to be used for feeding to the animals referred to in the same Article;
- 54. **'composting plant'** means a plant in which animal by-products or derived products are at least part of the material which is submitted to biological degradation under aerobic conditions;
- 55. **'co-incineration plant**' means any stationary or mobile plant whose main purpose is the generation of energy or the production of material products as defined in point 5 of Article 3 of Directive 2000/76/EC;
- 56. **'incineration plant**' means any stationary or mobile technical unit and equipment dedicated to the thermal treatment of waste as defined in point 4 of Article 3 of Directive 2000/76/EC;
- 57. **'petfood plant**' means premises or facilities for the production of petfood or flavouring innards, as referred to in Article 24(1)(e) of Regulation (EC) No 1069/2009;
- 58. '[<sup>F3</sup>processing plant' means premises or facilities for the processing of animal byproducts as referred to in Article 24(1)(a) of Regulation (EC) No 1069/2009, in which animal by-products are processed in accordance with Annex IV and/or Annex X;]
- 59. '[<sup>F4</sup>growing media' means materials, including potting soil, other than soil *in situ*, in which plants are grown and which is used independently from soil *in situ*.]

#### **Textual Amendments**

F1 Substituted by Commission Regulation (EU) No 294/2013 of 14 March 2013 amending and correcting Regulation (EU) No 142/2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (Text with EEA relevance).

- F2 Substituted by Commission Regulation (EU) No 1063/2012 of 13 November 2012 amending Regulation (EU) No 142/2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (Text with EEA relevance).
- **F3** Substituted by Commission Regulation (EU) 2015/9 of 6 January 2015 amending Regulation (EU) No 142/2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (Text with EEA relevance).
- F4 Inserted by Commission Regulation (EU) 2015/9 of 6 January 2015 amending Regulation (EU) No 142/2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (Text with EEA relevance).

# ANNEX II

# **RESTRICTIONS ON THE USE OF ANIMAL BY-PRODUCTS**

# CHAPTER I

# Intra-species recycling of fur animals

- 1. In Estonia, Latvia and Finland, the following fur animals may be fed with meat-andbone meal or other products which have been processed in accordance with Chapter III of Annex IV and which are derived from bodies or parts of bodies of animals of the same species:
- (a) [<sup>F5</sup>foxes (*Vulpes vulpes* and *Alopex lagopus*);]
- (b) raccoon dogs (*Nyctereutes procyonides*).

#### **Textual Amendments**

- F5 Substituted by Commission Regulation (EU) No 749/2011 of 29 July 2011 amending Regulation (EU) No 142/2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (Text with EEA relevance).
- 2. In Estonia and Latvia, fur animals of the species American mink (*Mustela vison*) may be fed with meat-and-bone meal or other products which have been processed in accordance with the processing methods set out in Chapter III of Annex IV and which are derived from bodies or parts of bodies of animals of the same species.
- 3. The feeding referred to in points 1 and 2 shall take place under the following conditions:
- (a) Feeding shall only take place in farms:

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Commission Regulation (EU) No 142/2011. (See end of Document for details)

- (i) which have been registered by the competent authority on the basis of an application that is accompanied by documentation proving that there is no reason to suspect the presence of the TSE agent in the population of the species covered by the application;
- (ii) where an appropriate surveillance system for transmissible spongiform encephalopathies (TSEs) in fur animals is in place on the farm and includes regular laboratory testing of samples for TSE;
- (iii) which have provided appropriate guarantees that no animal by-product or meat-and-bone meal or other products which have been processed in accordance with Chapter III of Annex IV and which are derived from those animals or their offspring may enter the food or feed chain of other animals than fur animals;
- (iv) which have had no known contact with any farm with a suspected or confirmed outbreak of TSE;
- (v) where the operator of the registered farm ensures that:
  - the carcases of fur animals intended for feeding to animals of the same species are handled and processed separately from carcases not authorised for that purpose,
  - fur animals fed with meat-and-bone meal or other products which have been processed in accordance with Chapter III of Annex IV and which are derived from animals of the same species are kept separate from animals not being fed with products derived from animals of the same species,
  - the farm complies with the requirements set out in point 2 of Section 1 of Chapter II of Annex VI and point (2)(b)(ii) of Chapter II of Annex VIII.
- (b) The operator of the farm shall ensure that meat-and-bone meal or other products derived from one species and intended for the feeding of the same species must:
  - have been processed in a processing plant approved under Article 24(1)(a) of Regulation (EC) No 1069/2009 and using only processing methods 1 to 5 or processing method 7 as set out in Chapter III of Annex IV to this Regulation;
  - (ii) have been produced from healthy animals killed for the production of fur.
- (c) In the event of any known or suspected contact with any farm with a suspected or confirmed outbreak of TSE, the operator of the farm must immediately:
  - (i) inform the competent authority of such contact;
  - (ii) cease the dispatch of fur animals to any destination without a written authorisation of the competent authority.

# CHAPTER II

#### Feeding of farmed animals with herbage

The following conditions shall apply to the feeding of farmed animals with herbage from land, either by direct access of the animals to that land or by using cut herbage as feed, provided that organic fertilisers or soil improvers have been applied to that land:

- (a) The waiting period of at least 21 days referred to in Article 11(1)(c) of Regulation (EC) No 1069/2009 must have been observed,
- (b) Only organic fertilisers and soil improvers have been used which comply with Article 32(1) and (2) of Regulation (EC) No 1069/2009 and with Chapter II of Annex XI hereto.

However, those conditions shall not apply, provided only the following organic fertilisers or soil improvers have been applied to land:

- (a) manure and guano;
- (b) digestive tract content, milk, milk-based products, milk-derived products, colostrum and colostrum products, which the competent authority does not consider to present a risk for the spread of any serious animal disease.

# [<sup>F6</sup>ANNEX III

# DISPOSAL, RECOVERY AND USE AS A FUEL]

#### **Textual Amendments**

**F6** Substituted by Commission Regulation (EU) No 592/2014 of 3 June 2014 amending Regulation (EU) No 142/2011 as regards the use of animal by-products and derived products as a fuel in combustion plants (Text with EEA relevance).

# CHAPTER I

## GENERAL REQUIREMENTS FOR INCINERATION AND CO-INCINERATION

#### Section 1

## **General conditions**

- 1. Operators of incineration and co-incineration plants referred to in Article 6(1)(b) of this Regulation shall ensure that the following hygiene conditions are met in the plants under their control:
- (a) Animal by-products and derived products must be disposed of as soon as possible after arrival, in accordance with conditions laid down by the competent authority. They shall be stored properly until disposal, in accordance with conditions laid down by the competent authority.

- (b) Plants must have appropriate arrangements for the cleaning and disinfection of containers and vehicles in place, in particular in a designated area from which wastewater is disposed of in accordance with Union legislation, to avoid risks of contamination.
- (c) Plants must be located on a well-drained hardstanding.
- (d) Plants must have appropriate arrangements for protection against pests, such as insects, rodents and birds. A documented pest control programme must be used for that purpose.
- (e) Staff must have access to adequate facilities for personal hygiene such as lavatories, changing rooms and washbasins, if necessary to prevent risks of contamination.
- (f) Cleaning procedures must be established and documented for all parts of the premises. Suitable equipment and cleaning agents must be provided for cleaning.
- (g) Hygiene control must include regular inspections of the environment and equipment. Inspection schedules and results must be documented and maintained for at least two years.
- 2. The operator of an incineration or co-incineration plant shall take all necessary precautions concerning the reception of animal by-products or derived products to prevent, or limit as far as practicable, direct risks to human or animal health.
- 3. Animals must not have access to the plants, animal by-products and derived products that are awaiting incineration or co-incineration or to ash resulting from the incineration or co-incineration of animal by-products.
- 4. If the incineration or co-incineration plant is located on a livestock holding:
- (a) there must be total physical separation between the incineration or co-incineration equipment and the livestock and their feed and bedding, with fencing where necessary;
- (b) equipment must be dedicated entirely to the operation of the incinerator and not used elsewhere on the holding or, alternatively, cleaned and disinfected before such use;
- (c) personnel working in the plant must change their outer clothing and footwear before handling livestock or livestock feed.
- 5. The storage of animal by-products and derived products that are awaiting incineration or co-incineration and of ashes must be in covered, correctly identified and, if appropriate, leak proof containers.
- 6. Incompletely incinerated animal by-products must be reincinerated or disposed of by other means, other than by disposal in an authorised landfill, in accordance with Articles 12, 13 and 14, as applicable, of Regulation (EC) No 1069/2009.

# Section 2

## **Operating conditions**

Incineration or co-incineration plants shall be designed, equipped, built and operated in such a way that the gas resulting from the process is raised in a controlled and homogeneous fashion, even under the most unfavourable conditions, to a temperature of 850 °C for at least 2 seconds or to a temperature of 1 100 °C for 0.2 seconds, as measured near the inner wall or at another

representative point of the chamber where the incineration or the co-incineration is carried out, as authorised by the competent authority.

## Section 3

## **Incineration and co-incineration residues**

- 1. Incineration and co-incineration residues shall be minimised in their amount and harmfulness. Such residues must be recovered, where appropriate, directly in the plant or outside it in accordance with relevant Union legislation or disposed of in an authorised landfill.
- 2. Transport and intermediate storage of dry residues, including dust, shall take place in such a way as to prevent dispersal in the environment, such as in closed containers.

# Section 4

## Measurement of temperature and of other parameters

- 1. Techniques shall be used to monitor the parameters and conditions relevant to the incineration or co-incineration process.
- 2. The approval issued by the competent authority, or conditions attached to it, shall lay down temperature measurement requirements.
- 3. The functioning of any automated monitoring equipment shall be subject to control and to an annual surveillance test.
- 4. Temperature measurement results shall be recorded and presented in an appropriate fashion to enable the competent authority to verify compliance with the permitted operating conditions laid down in this Regulation in accordance with procedures to be decided upon by that authority.

# Section 5

#### Abnormal operating

In the case of a breakdown, or abnormal operating conditions of an incineration plant or a coincineration plant, the operator shall reduce or close down operations as soon as practicable until normal operations can be resumed.

# CHAPTER II

# HIGH-CAPACITY INCINERATION AND CO-INCINERATION PLANTS

#### Section 1

#### **Specific operating conditions**

Incineration or co-incineration plants treating only animal by-products and derived products with a capacity of more than 50 kg per hour (high-capacity plants) and which are not required to have a permit to operate in accordance with Directive 2000/76/EC shall comply with the following conditions:

- (a) The plants must be equipped for each line with at least one auxiliary burner. This burner shall be switched on automatically when the temperature of the combustion gases after the last injection of combustion air falls below 850 °C or 1 100 °C, as applicable. It must also be used during plant start-up and shut-down operations to ensure that the temperature of 850 °C or of 1 100 °C, as applicable, is maintained at all times during these operations and as long as unburned material is in the chamber where the incineration or co-incineration is carried out.
- (b) When animal by-products or derived products are introduced into the chamber where the incineration or co-incineration is carried out by a continuous process, the plant must operate an automatic system to prevent the introduction of animal by-products or derived products at start-up, until the temperature of 850 °C or of 1 100 °C, as applicable, has been reached, and whenever the temperature is not maintained.
- (c) The operator must operate the incineration plant in such manner that a level of incineration is achieved such that the slag and bottom ashes total organic carbon content is less than 3 % or their loss on ignition is less than 5 % of the dry weight of the material. If necessary, appropriate techniques of pre-treatment shall be used.

#### Section 2

#### Water discharges

- 1. Sites of high capacity plants, including associated storage areas for animal byproducts, shall be designed in such a way as to prevent unauthorised and accidental release of any polluting substances into soil, surface water and groundwater.
- 2. Storage capacity shall be provided for contaminated rainwater run-off from the plant site or for contaminated water arising from spillage or firefighting operations.

The operator shall, if necessary, ensure that such rainwater and such water can be tested and treated before discharge, when necessary.

#### CHAPTER III

# LOW-CAPACITY INCINERATION AND CO-INCINERATION PLANTS

Incineration and co-incineration plants treating only animal by-products and derived products with a maximum capacity of less than 50 kg of animal by-products per hour or per batch (low-

capacity plants) and which are not required to have a permit to operate in accordance with Directive 2000/76/EC shall:

- (a) [<sup>F3</sup>only be used for the disposal of:
  - (i) dead pet animals referred to in Article 8(a)(iii) of Regulation (EC) No 1069/2009;
  - (ii) Category 1 materials referred to in Article 8(b), (e) and (f), Category 2 materials referred to in Article 9 or Category 3 materials referred to in Article 10 of that Regulation; and
  - (iii) dead individually identified equine animals from holdings not subject to health restrictions in accordance with Article 4(5) or 5 of Directive 2009/156/EC, if authorised by the Member State;]
- (b) when Category 1 materials referred to in Article 8(b) of Regulation (EC) No 1069/2009 are introduced into the low-capacity plant, be equipped with an auxiliary burner;
- (c) operate in such way that the animal by-products are completely reduced to ash.

# [<sup>F7</sup>CHAPTER IV

# GENERAL REQUIREMENTS FOR THE USE OF ANIMAL BY-PRODUCTS AND DERIVED PRODUCTS AS A FUEL

# Section 1

# General requirements regarding the combustion of animal by-products and derived products as a fuel

- 1. Operators of combustion plants referred to in Article 6(6) shall ensure that the following conditions are met in the combustion plants under their control:
- (a) Animal by-products and derived products intended to be used as a fuel must be utilised for that purpose as soon as possible or safely stored until used.
- (b) The combustion plants must have in place appropriate measures to ensure that cleaning and disinfection of containers and vehicles are carried out in a designated area of their premises from which the wastewater can be collected and disposed of in accordance with Union legislation, to avoid risks of contamination of the environment.

By way of derogation from the requirements set out in the first subparagraph, containers and vehicles used for the transport of rendered fats may be cleaned and disinfected at the plant of loading or at any other plant approved or registered under Regulation (EC) No 1069/2009.

- (c) The combustion plants must be located on a well-drained hard standing.
- (d) The combustion plants must have appropriate measures in place for the protection against pests. A documented pest control programme must be used for that purpose.

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Changes to legislation: There are currently no known outstanding effects for the
Commission Regulation (EU) No 142/2011. (See end of Document for details)

- (e) Staff must have access to adequate facilities for personal hygiene such as lavatories, changing rooms and washbasins, if necessary, to prevent risks of contamination of equipment for handling of farmed animals or their feedstuffs.
- (f) Cleaning and disinfection procedures, must be established and documented for all parts of the combustion plant. Suitable equipment and cleaning agents must be provided for cleaning.
- (g) Hygiene control must include regular inspections of the environment and equipment. Inspection schedules and results must be documented and retained for a period of at least two years.
- (h) Where rendered fats are used as a fuel for combustion in stationary internal combustion engines located within approved or registered food or feed processing plants, the processing of food or feed on the same site must take place under strict conditions of separation.
- 2. Operators of the combustion plants shall take all necessary precautions concerning the reception of animal by-products or derived products to prevent or limit as far as practicable, risks to human or animal health and the environment.
- 3. Animals must not have access to the combustion plant or to the animal by-products and derived products awaiting combustion or the ash resulting from the combustion.
- 4. Where the combustion plant is located on a holding keeping animals of food producing species:
- (a) there must be total physical separation between the combustion equipment and the animals including their feed and bedding;
- (b) equipment must be dedicated entirely to the operation of the combustion plant and not used elsewhere on the holding unless it had been effectively cleaned and disinfected before such use;
- (c) personnel working in the combustion plant must change their outer clothing and footwear and take personal hygiene measures before handling animals on this or any other holding or their feed or bedding material.
- 5. The animal by-products and derived products that are awaiting combustion as a fuel and the combustion residues must be stored in a closed and covered dedicated area, or in covered and leak-proof containers.
- 6. The combustion of animal by-products or derived products shall be carried out under conditions which prevent cross-contamination of feed for animals.

# Section 2

#### **Operating conditions of combustion plants**

1. Combustion plants must be designed, built, equipped and operated in such a way that even under the most unfavourable conditions the animal by-products and derived products are treated for at least for 2 seconds at a temperature of 850 °C or for at least 0,2 seconds at a temperature of 1 100 °C.

2. The gas resulting from the process is raised in a controlled and homogeneous fashion for 2 seconds to a temperature of 850 °C or for 0,2 seconds to a temperature of 1 100 °C.

The temperature must be measured near the inner wall or at another representative point of the combustion chamber, as authorised by the competent authority.

- 3. Automated techniques shall be used to monitor the parameters and conditions relevant to the combustion process.
- 4. Temperature measurement results shall be recorded automatically and presented in an appropriate fashion to enable the competent authority to verify compliance with the permitted operating conditions referred to in points 1 and 2 in accordance with procedures to be decided upon by the relevant authority.
- 5. The operator of a combustion plant shall ensure that the fuel is combusted in such a way that the total organic carbon content of the slags and bottom ashes is less than 3 % or their loss on ignition is less than 5 % of the dry weight of the material.

# Section 3

# **Combustion residues**

- 1. Combustion residues shall be minimised in their amount and harmfulness. Such residues must be recovered, or where it is not appropriate, disposed of or used in accordance with relevant Union legislation.
- 2. The transport and intermediate storage of dry residues, including dust, shall take place in closed containers or in another way which prevents dispersal into the environment.

# Section 4

# Breakdown or abnormal operating conditions

- 1. The combustion plant shall be equipped with facilities which automatically shut down operations in the case of a breakdown or abnormal operating conditions until normal operations can be resumed.
- 2. Incompletely combusted animal by-products and derived products must be combusted again or disposed of by means referred to in Articles 12, 13 and 14 of Regulation (EC) No 1069/2009 other than disposal in an authorised landfill.

# **Textual Amendments**

**F7** Inserted by Commission Regulation (EU) No 592/2014 of 3 June 2014 amending Regulation (EU) No 142/2011 as regards the use of animal by-products and derived products as a fuel in combustion plants (Text with EEA relevance).

# CHAPTER V

## TYPES OF PLANTS AND FUELS THAT MAY BE USED FOR COMBUSTION AND SPECIFIC REQUIREMENTS FOR PARTICULAR TYPES OF PLANTS

- A. Stationary internal combustion engines
- 1. Starting material:

For this process, a fat fraction derived from animal by-products of all categories may be used provided it meets the following conditions:

- (a) unless fish oil or rendered fat is used which has been produced in accordance with Section VIII or XII of Annex III to Regulation (EC) No 853/2004, respectively, the fat fraction derived from animal by-products must first be processed using:
  - (i) in the case of a fat fraction of Category 1 and 2 materials, any of the processing methods 1 to 5 as set out in Chapter III of Annex IV.

Where this fat is moved by a closed conveyer system, which may not be bypassed, and provided such a system has been authorised by the competent authority, from the processing plant for immediate direct combustion the permanent marking with glyceroltriheptanoate (GTH) referred to in point 1 of Chapter V of Annex VIII shall not be required;

- (ii) in the case of a fat fraction of Category 3 material, any of the processing methods 1 to 5 or processing method 7 as set out in Chapter III of Annex IV;
- (iii) in the case of the materials derived from fish, any of the processing methods 1 to 7 as set out in Chapter III of Annex IV;
- (b) the fat fraction must be separated from the protein and in the case of fat from ruminant origin which is intended to be combusted in another plant, insoluble impurities in excess of 0,15 % by weight must be removed.
- 2. Methodology:

Combustion of animal fat as a fuel in a stationary internal combustion engine shall be carried out as follows:

- (a) the fat fractions referred to in points 1(a) and (b) must be combusted:
  - (i) under the conditions laid down in Section 2(1) of Chapter IV; or
  - (ii) using process parameters achieving an equivalent outcome as the conditions under (i) and which are authorised by the competent authority;
- (b) the combustion of material of animal origin other than animal fat must not be permitted;
- (c) the animal fat derived from Category 1 or Category 2 combusted in premises approved or registered in accordance with Regulations (EC) No 852/2004, (EC) No 853/2004, 183/2005, or in public places must have been processed with processing method 1 as set out in Chapter III of Annex IV;
- (d) the combustion of animal fat must be carried out in accordance with Union legislation for the protection of the environment, in particular, with reference to the standards

and requirements of that legislation and the requirements regarding best available techniques for the control and monitoring of emissions.

3. Operating conditions:

By way of derogation from the requirements set out in the first paragraph of point 2 of Section 2 of Chapter IV, requirements based on other process parameters, which ensure an equivalent environmental outcome may be authorised by the competent authority responsible for environmental issues.

- B. On-farm combustion plants in which poultry manure is used as a fuel
- 1. Type of plant:

On-farm combustion plant with a total rated thermal input not exceeding 5 MW.

2. Starting material and scope:

Exclusively unprocessed poultry manure, as referred to in Article 9(a) of Regulation (EC) No 1069/2009, to be used as a fuel for combustion in accordance with the requirements set out in point 3 to 5.

The combustion of other animal by-products or derived products and of manure of other species or generated outside the holding shall not be allowed for use as a fuel in on-farm combustion plants referred to in point 1.

- 3. Specific requirements for poultry manure used as a fuel for combustion:
- (a) The manure shall be stored securely in a closed storage area to minimise the need for further handling and to prevent cross contamination with other areas on a holding keeping animals of food producing species.
- (b) The on-farm combustion plant must be equipped with:
  - (i) an automatic fuel management system to place the fuel directly in the combustion chamber without further handling;
  - (ii) an auxiliary burner which must be used during start-up and shut-down operations to ensure that the temperature requirements set out in Section 2(2) of Chapter IV are met at all times during those operations and as long as unburned material is in the combustion chamber.
- 4. Emission limit values and monitoring requirements:
- (a) The emissions of sulphur dioxide, nitrogen oxides (namely the sum of nitrogen monoxide and nitrogen dioxide, expressed as nitrogen dioxide) and particulate matter shall not exceed the following emission limit values, expressed in mg/Nm<sup>3</sup> at a temperature of 273,15 K, a pressure of 101,3 kPa and an oxygen content of 11 per cent, after correction for the water vapour content of the waste gases:

Pollutant	Emission limit value in mg/Nm <sup>3</sup>
Sulphur dioxide	50
Nitrogen oxides (as NO <sub>2</sub> )	200
Particulate matter	10

(b) The operator of the on-farm combustion plant shall carry out at least annual measurements of sulphur dioxide, nitrogen oxides and particulate matter.

As an alternative to the measurements referred to in the first subparagraph, other procedures, verified and approved by the competent authority, may be used to determine the emissions of sulphur dioxide.

Monitoring shall be carried out by or on behalf of the operator in accordance with CEN standards. Where CEN standards are not available, ISO, national or other international standards which ensure the provision of data of an equivalent scientific quality shall apply.

- (c) All results shall be recorded, processed and presented in such a way as to enable the competent authority to verify compliance with the emission limit values.
- (d) For on-farm combustion plants applying secondary abatement equipment in order to meet the emission limit values, the effective operation of that equipment shall be monitored continuously and the results thereof recorded.
- (e) In the event of non-compliance with the emission limit values referred to in point (a) or where an on-farm combustion plant does not meet the requirements of point 1 of Section 2 of Chapter IV, operators shall immediately inform the competent authority and take the measures necessary to ensure that compliance is restored within the shortest possible time. Where compliance cannot be restored, the competent authority shall suspend the operation of the plant and withdraw its approval.
- 5. Changes of operation and breakdowns:
- (a) The operator shall notify the competent authority of any planned change of the onfarm combustion plant which would affect its emissions at least one month before the date on which the change takes place.
- (b) The operator shall take the necessary measures to ensure that the periods of start-up and shut-down of the on-farm combustion plant and of any malfunctions are kept as short as possible. In the case of a malfunction or a breakdown of secondary abatement equipment, the operator shall immediately inform the competent authority.]

#### ANNEX IV

## PROCESSING

## CHAPTER I

# **REQUIREMENTS FOR PROCESSING PLANTS AND CERTAIN OTHER PLANTS AND ESTABLISHMENTS**

#### Section 1

#### **General conditions**

- Processing plants shall meet the following requirements, for processing by pressure sterilisation or in accordance with the processing methods referred to in Article 15(1) (b) of Regulation (EC) No 1069/2009:
- (a) Processing plants must not be situated on the same site as slaughterhouses or other establishments which have been approved or registered in accordance with Regulation (EC) No 852/2004 or Regulation (EC) No 853/2004, unless the risks to public and animal health resulting from the processing of animal by-products, which originate from such slaughterhouses or other establishments, are mitigated by compliance with at least the following conditions:
  - (i) the processing plant must be physically separated from the slaughterhouse or other establishment, where appropriate by locating the processing plant in a building that is completely separated from the slaughterhouse or other establishment;
  - (ii) the following must be installed and operated in the processing plant:
    - a conveyer system which links the processing plant to the slaughterhouse or other establishment and which may not be bypassed,
    - separate entrances, reception bays, equipment and exits for both the processing plant and the slaughterhouse or establishment;
  - (iii) measures must be taken to prevent the spreading of risks through the operation of personnel which is employed in the processing plant and in the slaughterhouse or other establishment;
  - (iv) unauthorised persons and animals must not have access to the processing plant.

By way of derogation from points (i) to (iv), in the case of processing plants processing Category 3 material, the competent authority may authorise other conditions instead of those set out in those points, aimed at mitigating the risks to public and animal health, including the risks arising from the processing of Category 3 material, which originates from off-site establishments approved or registered in accordance with Regulation (EC) No 852/2004 or Regulation (EC) No 853/2004.

Member States shall inform the Commission and the other Member States in the framework of the Standing Committee on the Food Chain and Animal Health referred

to in Article 52(1) of Regulation (EC) No 1069/2009 of the use made of this derogation by their competent authorities;

- (b) The processing plant must have a clean and unclean sector, adequately separated. The unclean sector must have a covered place to receive animal by-products and must be constructed in such a way that it is easy to clean and disinfect. Floors must be laid in such a way as to facilitate the draining of liquids;
- (c) The processing plant must have adequate facilities including lavatories, changing rooms and washbasins for staff;
- (d) The processing plant must have sufficient production capacity for hot water and steam for the processing of animal by-products;
- (e) The unclean sector must, if appropriate, contain equipment to reduce the size of animal by-products and equipment for loading the crushed animal by-products into the processing unit;
- (f) Where heat treatment is required, all installations must be equipped with:
  - (i) measuring equipment to monitor temperature against time and, if applicable for the processing method used, pressure at critical points;
  - (ii) recording devices to record continuously the results of these measurements in a way so that they remain accessible for the purpose of checks and official controls;
  - (iii) an adequate safety system to prevent insufficient heating;
- (g) To prevent recontamination of the derived product by the introduction of animal byproducts, there must be a clear separation between the area of the plant where incoming material for processing is unloaded and the areas set aside for the processing of that product and the storage of the derived product.
- 2. The processing plant must have adequate facilities for cleaning and disinfecting the containers or receptacles in which animal by-products are received and the means of transport, other than ships, in which they are transported.
- 3. Adequate facilities must be provided for the disinfecting of vehicle wheels and the other parts of the vehicle, as appropriate, on leaving the unclean sector of the processing plant.
- 4. All processing plants must have a waste-water disposal system meeting the requirements set out by the competent authority in accordance with Union legislation.
- 5. The processing plant must have its own laboratory or make use of the services of an external laboratory. The laboratory must be equipped to carry out necessary analyses and be approved by the competent authority on the basis of an assessment of the capacity of the laboratory to carry out those analyses, be accredited according to internationally recognised standards or be subject to regular controls by the competent authority, to assess the capacity of the laboratory to carry out those analyses.
- 6. If on the basis of a risk assessment, the volume of products treated requires the regular or permanent presence of the competent authority, the processing plants must have an adequately equipped lockable room for the exclusive use of the inspection service.

#### Section 2

#### Wastewater treatment

1. Processing plants processing Category 1 material and other premises where specified risk material is removed, slaughterhouses and processing plants processing Category 2 material shall have a pre-treatment process for the retention and collection of animal material as an initial step in the treatment of wastewater.

The equipment used in the pre-treatment process shall consist of drain traps or screens with a pertures with a filter pore or a mesh size of no more than 6 mm in the downstream end of the process or equivalent systems that ensure that the solid particles in the wastewater passing through them are no more than 6 mm.

- 2. Wastewater from the premises as referred to in point 1 must enter a pre-treatment process which shall ensure that all wastewater has been filtered through the process before being drained off the premises. No grinding, maceration or any other processing or application of pressure shall be carried out which could facilitate the passage of solid animal material through the pre-treatment process.
- 3. All animal material retained in the pre-treatment process in premises as referred to in point 1 shall be collected and transported as Category 1 or Category 2 material, as appropriate, and disposed of in accordance with Regulation (EC) No 1069/2009.
- 4. Wastewater having passed the pre-treatment process in premises referred to in point 1 and wastewater from other premises handling or processing animal by-products shall be treated in accordance with Union legislation, without restrictions in accordance with this Regulation.
- 5. In addition to the requirements laid down in point 4, the competent authority may oblige operators to treat wastewater originating in the unclean sector of processing plants and in plants or establishments carrying out intermediate operations with Category 1 material or Category 2 material or storing Category 1 material or Category 2 material, in accordance with conditions which ensure that risks from pathogens are mitigated.
- 6. Without prejudice to points 1 to 5, the disposal of animal by-products, including blood and milk, or derived products through the wastewater stream shall be prohibited.

However, Category 3 material comprising of centrifuge or separator sludge may be disposed of through the wastewater stream, provided that it has been subject to one of the treatments for centrifuge or separator sludge set out in Part III of Section 4 of Chapter II of Annex X hereto.

#### Section 3

# Specific requirements for the processing of Category 1 and Category 2 materials

The layout of processing plants processing Category 1 and Category 2 materials must ensure the total separation of Category 1 material from Category 2 material from reception of the raw material until dispatch of the resulting derived product, unless a mixture of Category 1 material and Category 2 material is processed as Category 1 material.

#### Section 4

#### Specific requirements for the processing of Category 3 materials

The following requirements shall apply in addition to the general conditions set out in Section 1:

- 1. Processing plants processing Category 3 materials shall not be located at the same site as processing plants processing Category 1 or Category 2 materials, unless located in a completely separate building.
- 2. However, the competent authority may authorise the processing of Category 3 material on a site where handling or processing of Category 1 or Category 2 material takes place, if cross-contamination is prevented due to:
  - (a) the layout of the premises, in particular the arrangements for the reception, and by way of the further handling of raw materials;
  - (b) the layout and the management of the equipment used for processing, including the layout and the management of separate processing lines or of cleaning procedures which are excluding the propagation of any possible risks to public and animal health; and
  - (c) the layout and the management of the areas for the temporary storage of the end products.
- 3. Processing plants processing Category 3 material shall have in place an installation to check the presence of foreign bodies, such as packaging material or metallic pieces, in the animal by-products or derived products, if they are processing materials which are destined for feeding. Such foreign bodies shall be removed before or during processing.

# CHAPTER II

## HYGIENE AND PROCESSING REQUIREMENTS

#### Section 1

# General hygiene requirements

In addition to the general hygiene requirements provided for in Article 25 of Regulation (EC) No 1069/2009, processing plants shall have a documented pest control programme in place for the implementation of the arrangements for protection against pests, such as insects, rodents and birds, referred to in Article 25(1)(c) of that Regulation.

# Section 2

## **General processing requirements**

1. Accurately calibrated gauges/recorders must be used to monitor continuously the processing conditions. Records must be kept to show the date of calibration of gauges/ recorders.

2. Material that may not have received the specified heat treatment, such as material discharged at start up or leakage from cookers, must be recirculated through the heat treatment or collected and reprocessed or disposed of in accordance with Regulation (EC) No 1069/2009.

# Section 3

# Processing methods for Category 1 and Category 2 material

Unless the competent authority requires the application of pressure sterilisation (method 1), Category 1 and Category 2 material shall be processed in accordance with processing methods 2, 3, 4 or 5 as referred to in Chapter III.

# Section 4

## Processing of Category 3 material

- 1. The critical control points that determine the extent of the heat treatments applied in processing shall include for each processing method as specified in Chapter III:
- (a) raw material particle size;
- (b) temperature achieved in the heat treatment process;
- (c) pressure, if applied to the raw material;
- (d) duration of the heat treatment process or feed rate to a continuous system. Minimum processing standards must be specified for each applicable critical control point.
- 2. In the case of chemical treatments which have been authorised by the competent authority as processing method 7 in accordance with point G of Chapter III, the critical control points that determine the extent of the chemical treatments applied shall include the pH adjustment achieved.
- 3. Records shall be maintained for at least two years to show that the minimum process values for each critical control point are applied.
- 4. Category 3 material shall be processed in accordance with any of the processing methods 1 to 5 or processing method 7, or, in the case of material originating from aquatic animals, with any of the processing methods 1 to 7, as referred to in Chapter III.

# CHAPTER III

# STANDARD PROCESSING METHODS

A. Processing method 1 (pressure sterilisation) Reduction

1. If the particle size of the animal by-products to be processed is more than 50 millimetres, the animal by-products must be reduced in size using appropriate equipment, set so that the particle size after reduction is no greater than 50 millimetres. The effectiveness of the equipment must be checked daily and its condition recorded.

If checks disclose the existence of particles larger than 50 millimetres, the process must be stopped and repairs made before the process is resumed.

Time, temperature and pressure

- 2. The animal by-products with the particle size of no greater than 50 millimetres must be heated to a core temperature of more than 133 °C for at least 20 minutes without interruption at a pressure (absolute) of at least 3 bars. The pressure must be produced by the evacuation of all air in the sterilisation chamber and the replacement of the air by steam ('saturated steam'); the heat treatment may be applied as the sole process or as a pre- or post-process sterilisation phase.
- 3. The processing may be carried out in batch or continuous systems.
- B. Processing method 2

Reduction

1. If the particle size of the animal by-products to be processed is more than 150 millimetres, the animal by-products must be reduced in size using appropriate equipment, set so that the particle size after reduction is no greater than 150 millimetres. The effectiveness of the equipment must be checked daily and its condition recorded. If checks disclose the existence of particles larger than 150 millimetres, the process must be stopped and repairs made before the process is resumed.

Time, temperature and pressure

2. After reduction the animal by-products must be heated in a manner which ensures that a core temperature greater than 100 °C is achieved for at least 125 minutes, a core temperature greater than 110 °C is achieved for at least 120 minutes and a core temperature greater that 120 °C is achieved for at least 50 minutes.

The core temperatures may be achieved consecutively or through a coincidental combination of the time periods indicated.

3. The processing must be carried out in a batch system.

C. Processing method 3

Reduction

1. If the particle size of the animal by-products to be processed is more than 30 millimetres, the animal by-products must be reduced in size using appropriate equipment, set so that the particle size after reduction is no greater than 30 millimetres. The effectiveness of the equipment must be checked daily and its condition recorded. If checks disclose the existence of particles larger than 30 millimetres, the process must be stopped and repairs made before the process is resumed.

Time, temperature and pressure

2. After reduction the animal by-products must be heated in a manner which ensures that a core temperature greater than 100 °C is achieved for at least 95 minutes, a core temperature greater than 110 °C is achieved for at least 55 minutes and a core temperature greater that 120 °C is achieved for at least 13 minutes.

The core temperatures may be achieved consecutively or through a coincidental combination of the time periods indicated.

- 3. The processing may be carried out in batch or continuous systems.
- D. Processing method 4

# Reduction

1. If the particle size of the animal by-products to be processed is more than 30 millimetres, the animal by-products must be reduced in size using appropriate equipment, set so that the particle size after reduction is no greater than 30 millimetres. The effectiveness of the equipment must be checked daily and its condition recorded. If checks disclose the existence of particles larger than 30 millimetres, the process must be stopped and repairs made before the process is resumed.

Time, temperature and pressure

2. After reduction the animal by-products must be placed in a vessel with added fat and heated in a manner which ensures that a core temperature greater than 100 °C is achieved for at least 16 minutes, a core temperature greater than 110 °C is achieved for at least 13 minutes, a core temperature greater than 120 °C is achieved for at least eight minutes and a core temperature greater that 130 °C is achieved for at least three minutes.

The core temperatures may be achieved consecutively or through a coincidental combination of the time periods indicated.

3. The processing may be carried out in batch or continuous systems.

E. Processing method 5

Reduction

1. If the particle size of the animal by-products to be processed is more than 20 millimetres, the animal by-products must be reduced in size using appropriate equipment, set so that the particle size after reduction is no greater than 20 millimetres. The effectiveness of the equipment must be checked daily and its condition recorded. If checks disclose the existence of particles larger than 20 millimetres, the process must be stopped and repairs made before the process is resumed.

Time, temperature and pressure

2. After reduction the animal by-products must be heated until they coagulate and then pressed so that fat and water are removed from the proteinaceous material. The proteinaceous material must then be heated in a manner which ensures that a core temperature greater than 80 °C is achieved for at least 120 minutes and a core temperature greater that 100 °C is achieved for at least 60 minutes.

The core temperatures may be achieved consecutively or through a coincidental combination of the time periods indicated.

- 3. The processing may be carried out in batch or continuous systems.
- F. Processing method 6 (for Category 3 animal by-products originating from aquatic animal or aquatic invertebrates only)

Reduction

- 1. The animal by-products must be reduced to a particle size which is no greater than:
- (a) 50 mm, in case of heat treatment in accordance with point 2(a); or
- (b) 30 mm, in case of heat treatment in accordance with point 2(b).

They must then be mixed with formic acid to reduce and maintain the pH to 4,0 or lower. The mixture must be stored for at least 24 hours pending further treatment. Time, temperature and pressure

- 2. After reduction, the mixture must be heated to:
- (a) a core temperature of at least 90 °C for at least 60 minutes; or
- (b) a core temperature of at least 70 °C for at least 60 minutes.

When using a continuous flow system, the progression of the product through the heat converter must be controlled by means of mechanical commands limiting its displacement in such way that at the end of the heat treatment operation the product has undergone a cycle which is sufficient in both time and temperature.

- 3. The processing may be carried out in batch or continuous systems.
- G. Processing method 7
- 1. Any processing method authorised by the competent authority where the following have been demonstrated by the operator to that authority:
- (a) the identification of relevant hazards in the starting material, in view of the origin of the material, and of the potential risks in view of the animal health status of the Member State or the area or zone where the method is to be used;
- (b) the capacity of the processing method to reduce those hazards to a level which does not pose any significant risks to public and animal health;
- (c) the sampling of the final product on a daily basis over a period of 30 production days in compliance with the following microbiological standards:
  - (i) Samples of material taken directly after the treatment:

Clostridium perfringens absent in 1 g of the products

 Samples of material taken during or upon withdrawal from storage: Salmonella: absence in 25g: n=5, c=0, m=0, M=0 Enterobacteriaceae: n=5, c=2; m=10; M=300 in 1 g

where:

n	=	number of samples to be tested;
m	=	threshold value for the number of
		bacteria; the result is considered satisfactory if the number of bacteria in all samples does not exceed m;
М	=	maximum value for the number of
		bacteria; the result is considered
		unsatisfactory if the number of
		bacteria in one or more samples is M or more; and
с	=	number of samples the bacterial count
C		of which may be between m and
		M, the samples still being considered
		acceptable if the bacterial count of the
		other samples is m or less.
		-

2. Details of the critical control points under which each processing plant satisfactorily complies with the microbiological standards must be recorded and maintained so that the operator and the competent authority can monitor the operation of the processing

plant. The information to be recorded and monitored must include the particle size, and, as appropriate, the critical temperature, the absolute time, pressure profile, raw material feed rate and fat recycling rate.

- 3. By way of derogation from point 1, the competent authority may authorise the use of processing methods which have been approved prior to the date of entry into application of this Regulation, in accordance with Chapter III of Annex V to Regulation (EC) No 1774/2002.
- 4. The competent authority shall permanently or temporarily suspend the application of processing methods referred to in points 1 and 3, if it obtains evidence that any of the circumstances specified in point 1(a) or (b) have substantially changed.
- 5. The competent authority shall inform the competent authority of another Member State upon request about the information at its disposal under points 1 and 2 in relation to an authorised processing method.

# CHAPTER IV

# ALTERNATIVE PROCESSING METHODS

# Section 1

# **General provisions**

[<sup>F5</sup>1. Materials resulting from the processing of Category 1 and 2 materials shall be permanently marked in accordance with the requirements for the marking of certain derived products set out in Chapter V of Annex VIII.

However, such marking shall not be required for the following materials referred to in Section 2:

- (a) biodiesel produced in accordance with point D;
- (b) hydrolysed materials referred to in point H;
- (c) mixtures of pig and poultry manure with quick lime produced in accordance with point I;
- (d) renewable fuels produced from rendered fats, which are derived from Category 2 materials, in accordance with point J.]
- 2. The competent authority of a Member State shall make the results of official controls available to the competent authority of another Member State upon request, when an alternative method is used for the first time in that Member State, in order to facilitate the introduction of the new alternative method.

# Section 2

# Processing standards

- A. Alkaline hydrolysis process
- 1. Starting material

For this process, animal by-products of all categories may be used.

2. Processing method

Alkaline hydrolysis shall be carried out according to the following processing standards:

(a) Either a sodium hydroxide (NaOH) or potassium hydroxide (KOH) solution (or a combination thereof) must be used in an amount that assures approximate molar equivalency to the weight, type and composition of the animal by-products to be digested.

In the case of high fat in the animal by-products that neutralises the base, the added base must be adjusted so that the molar equivalency referred to is achieved.

- (b) Animal by-products must be placed in a steel alloy container. The measured amount of alkali must be added either in solid form or as a solution as referred to in point (a).
- (c) The container must be closed and the animal by-products and alkali mixture must be heated to a core temperature of at least 150 °C and at a pressure (absolute) of at least 4 bars for at least:
  - (i) three hours without interruption;
  - (ii) six hours without interruption in case of treatment of animal by-products referred to in Article 8(a)(i) and (ii) of Regulation (EC) No 1069/2009.

However, materials derived from Category 1 materials comprising of animals killed in the context of TSE eradication measures which are either ruminants not requiring TSE testing or ruminants which have been tested with a negative result in accordance with Article 6(1) of Regulation (EC) No 999/2001 may be processed in accordance with point 2(c)(i) of this Section; or

- (iii) one hour without interruption in the case of animal by-products consisting of fish or of poultry materials.
- (d) The process must be carried out in a batch system and the material in the vessel must be constantly mixed in order to facilitate the digestion process until the tissues are dissolved and bones and teeth are softened; and
- (e) The animal by-products must be treated in such way that the requirements regarding time, temperature and pressure are achieved at the same time.
- B. High pressure high temperature hydrolysis process
- 1. Starting material

For this process, Category 2 and Category 3 materials may be used.

2. Processing method

High pressure high temperature hydrolysis shall be carried out according to the following processing standards:

(a) The animal by-products must be heated to a core temperature of at least 180 °C for at least 40 minutes without interruption at a pressure (absolute) of at least 12 bar, heated by indirect steam application to the biolytic reactor;

- (b) The process must be carried out in a batch and the material in the vessel must be constantly mixed; and
- (c) The animal by-products must be treated in such a manner that the requirements regarding time, temperature and pressure are achieved at the same time.
- C. High pressure hydrolysis biogas process
- 1. Starting material

For this process, animal by-products of all categories may be used.

2. Processing method

The high pressure hydrolysis biogas process shall be carried out according to the following processing standards:

- (a) The animal by-products must be first processed using processing method 1 (pressure sterilisation) as set out in Chapter III in an approved processing plant;
- (b) Following the process referred to in point (a), the defatted materials must be treated at a temperature of at least 220 °C for at least 20 minutes at a pressure (absolute) of at least 25 bar, heated in a two-step procedure, first by direct steam injection, secondly indirect in a coaxial heat exchanger;
- (c) The process must be carried out in a batch or continuous system and the material is constantly mixed;
- (d) The animal by-products must be treated in such a manner that the requirements regarding time, temperature and pressure are achieved at the same time;
- (e) The resulting material must then be mixed with water and anaerobically fermented (biogas transformation) in a biogas reactor;
- (f) In the case of starting material of Category 1, the entire process must take place on the same site and in a closed system and the biogas produced during the process must be combusted rapidly in the same plant at a minimum of 900 °C followed by rapid chilling ('quenching').
- D. Biodiesel production process
- 1. Starting material

For this process, a fat fraction derived from animal by-products of all categories may be used.

2. Processing method

Biodiesel production shall be carried out according to the following processing standards:

- (a) Unless fish oil or rendered fat are used which have been produced in accordance with Sections VIII or XII of Annex III to Regulation (EC) No 853/2004, respectively, the fat fraction derived from animal by-products must be first processed using:
  - (i) in the case of Category 1 or 2 materials, processing method 1 (pressure sterilisation) as set out in Chapter III; and
  - (ii) in the case of Category 3 materials, any of the processing methods 1 to 5 or processing method 7 or, in the case of material derived from fish, processing methods 1 to 7 as set out in Chapter III;

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Changes to legislation: There are currently no known outstanding effects for the	
Commission Regulation (EU) No 142/2011. (See end of Document for details)	

- (b) The processed fat must then be processed further using one of the following methods:
  - a process whereby the processed fat must be separated from the protein and in the case of fat from ruminant origin, insoluble impurities in excess of 0,15 % by weight must be removed, and the processed fat must be subsequently submitted to esterfication and transesterfication.

However, esterfication is not required for processed fat derived from Category 3 material. For esterfication the pH must be reduced to less than 1 by adding sulphuric acid ( $H_2SO_4$ ) or an equivalent acid and the mixture must be heated to 72 °C for at least two hours during which it must be intensely mixed.

Transesterfication must be carried out by increasing the pH to about 14 with potassium hydroxide or with an equivalent base at 35 °C to 50 °C for at least 15 minutes. Transesterfication shall be carried out twice under the conditions described in this point using a new base solution. This process must be followed by refinement of the products including vacuum distillation at 150 °C, leading to biodiesel;

- (ii) a process using equivalent process parameters authorised by the competent authority.
- E. Brookes' gasification process
- 1. Starting material

For this process, Category 2 and Category 3 material may be used.

2. Processing method

Brookes' gasification shall be carried out according to the following processing standards:

- (a) The afterburner chamber must be warmed up using natural gas;
- (b) The animal by-products must be loaded into the primary chamber of the gasificator and the door must be closed. The primary chamber must have no burners and must be heated instead by the transfer of heat by conduction from the afterburner, which must be underneath the primary chamber. The only air admitted to the primary chamber must be via three inlet valves mounted on the main door to enhance the efficiency of the process;
- (c) The animal by-products must be volatilised into complex hydrocarbons and the resultant gases must pass from the primary chamber via a narrow opening at the top of the back wall to the mixing and cracking zones, where they must be broken down into their constituent elements. Finally the gases must pass into the afterburner chamber where they must be burned in the flame of a natural gas fired burner in the presence of excess air;
- (d) Each process unit must have two burners and two secondary air fans for back-up in case of burner or fan failure. The secondary chamber must be designed to give a minimum residence time of two seconds at a temperature of at least 950 °C under all conditions of combustion;
- (e) On leaving the secondary chamber the exhaust gases must pass through a barometric damper at the base of the stack, which cools and dilutes them with ambient air, maintaining a constant pressure in the primary and secondary chambers;

- (f) The process must be carried out over a 24-hour cycle, which includes loading, processing, cool down and ash removal. At the end of the cycle the residual ash must be removed from the primary chamber by a vacuum extraction system into enclosed bags and sealed before transporting;
- (g) The gasification of material other than animal by-products must not be permitted.
- F. Combustion of animal fat in a thermal boiler process
- 1. Starting material

For this process, a fat fraction derived from animal by-products of all categories may be used.

2. Processing method

Combustion of animal fat in a thermal boiler shall be carried out according to the following processing standards:

- (a) Unless fish oil or rendered fat are used which has been produced in accordance with Sections VIII or XII of Annex III to Regulation (EC) No 853/2004, respectively, the fat fraction derived from animal by-products must first be processed using:
  - (i) in the case of fat fraction of Category 1 and 2 materials which is intended to be combusted in another plant,
    - for the fat fraction from the processing of ruminants which have been tested with a negative result in accordance with Article 6(1) of Regulation (EC) No 999/2001 and from the processing of animals, other than ruminants which require TSE testing, any of the processing methods 1 to 5 as set out in Chapter III of this Annex.
    - for the fat fraction from the processing of other ruminants, processing method 1 as referred in Chapter III; and
  - (ii) in the case of Category 1 and 2 materials intended for combustion within the same plant and in the case of Category 3 material, any of the processing methods 1 to 5 or processing method 7; in the case the materials are derived from fish, processing methods 1 to 7 as set out in Chapter III;
- (b) The fat fraction must be separated from the protein and in the case of fat from ruminant origin which is intended to be combusted in another plant, insoluble impurities in excess of 0,15 % by weight must be removed;
- (c) Following the process referred to in points (a) and (b), the fat must be:
  - (i) vaporised in a steam-raising boiler and combusted at a temperature of at least 1 100 °C for at least 0,2 seconds; or
  - (ii) processed using equivalent process parameters authorised by the competent authority;
- (d) The combustion of material of animal origin other than animal fat must not be permitted;
- (e) The combustion of the fat derived from Category 1 and Category 2 materials shall take place in the same plant where the fat is rendered with the aim of utilising the energy generated for the rendering processes. However, the competent authority may authorise the movement of that fat to other plants for combustion provided that:
  - (i) the plant of destination is authorised for the combustion;

- (ii) the processing of food or feed in an approved plant on the same premises takes place under strict conditions of separation;
- (f) The combustion must be carried out in accordance with Union legislation for the protection of the environment, in particular, with reference to the standards of that legislation regarding best available techniques for the control and monitoring of emissions.
- G. Thermomechanical biofuel production process
- 1. Starting material

For this process, manure and digestive tract content and Category 3 material may be used.

2. Processing method

Thermomechanical biofuel production shall be carried out according to the following processing standards:

- (a) The animal by-products must be loaded into a converter and subsequently treated at a temperature of 80 °C for a period of eight hours. During this period, the material must be constantly reduced in size using appropriate mechanical abrasion equipment.
- (b) The material must be subsequently treated at a temperature of 100 °C for at least two hours.
- (c) The particle size of the resulting material must not be larger than 20 millimetres;
- (d) The animal by-products must be treated in such a manner that the requirements regarding time, temperature and pressure set out in points (a) and (b) are achieved at the same time;
- (e) During the heat treatment of the material, evaporated water must be continually extracted from the air-space above the biofuel and must be passed through a stainless steel condenser. The condensate must be kept at a temperature of at least 70 °C for at least one hour before being discharged as wastewater;
- (f) After the heat treatment of the material, the resulting biofuel from the converter must then be discharged and automatically conveyed by a fully covered and interlocked conveyor to incineration or co-incineration on the same site;
- (g) The process must be carried out in a batch mode.

<sup>F8</sup>H.Hydrolysis with subsequent disposal

# **Textual Amendments**

- F8 Deleted by Commission Regulation (EU) 2015/9 of 6 January 2015 amending Regulation (EU) No 142/2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (Text with EEA relevance).
- [<sup>F9</sup>I. Lime treatment for pig and poultry manure
- 1. Starting materials

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Changes to legislation: There are currently no known outstanding effects for the
Commission Regulation (EU) No 142/2011. (See end of Document for details)

For this process, manure, as referred to in Article 9(a) of Regulation (EC) No 1069/2009, of pig and poultry origin may be used.

- 2. Processing method
- (a) The dry matter content of the manure must be determined by using the CEN EN 12880:2000<sup>(1)</sup> method 'Characterization of sludges. Determination of dry residue and water content'.

For this process, the dry matter content must be between 15 % and 70 %.

- (b) The amount of lime which has to be added must be determined in such way that one of the combinations of time and temperature set out in point (f) is achieved.
- (c) The particle size of the animal by-products to be processed must be no greater than 12 mm.

If necessary, the particles of the manure must be reduced in size in such a way that that maximum particle size is achieved.

(d) The manure must be mixed with quick lime (CaO) which has a medium to high reactivity of less than six minutes to achieve a 40 °C rise in temperature as per the criteria in the reactivity test 5.10 in the CEN EN 459-2:2002 method<sup>(2)</sup>.

The mixing must be carried out with two mixers which are operating in line, with two screws per mixer.

Both mixers must:

- (i) have a screw diameter of 0,55 m and a screw length of 3,5 m;
- (ii) operate with a power of 30 kW and a rotation speed of the screw of 156 rpm;
- (iii) have a treatment capacity of 10 tonnes per hour.

The mean blending duration must be approximately two minutes.

- (e) The mixture must be mixed for a period of at least six hours into a stockpile with a minimum size of two tonnes.
- (f) At monitoring points which must be introduced into the stockpile, continuous measurements must be carried out to demonstrate that the mixture in the stockpile reaches a pH of at least 12 during one of the following periods of time, during which period one of the corresponding following temperatures must be achieved:
- (i) 60 °C for 60 minutes; or
- (ii)  $70 \,^{\circ}\text{C}$  for 30 minutes.
- (g) The process must be carried out in a batch mode.
- (h) A permanent written procedure based on the HACCP principles must be put in place.
- (i) Operators may demonstrate to the competent authority, by way of a validation according to the following requirements, that a process using a mixing device which is different from the mixing device referred to in point (d) or using dolime (CaOMgO) instead of quick lime is at least as efficient as the process set out in points (a) to (h):

That validation must:

- demonstrate that by using the different mixing device to that referred to in point (d) or the dolime, as applicable, a mixture with manure can be produced which achieves the parameters for pH, time and temperature referred to in point (f);
- be based on monitoring of time and temperature at the base, the middle and at the top of the stockpile, with a representative number of monitoring points (at least four monitoring points in the basal zone, which are located at a maximum of 10 cm above the base and at a maximum of 10 cm below the top, one monitoring point in the middle half way between base and the top of stockpile, and four monitoring points in the marginal zone at the top of the pile, which are located at a maximum of 10 cm below the stockpile);
- be carried out during two periods of at least 30 days, of which one must be in the cold season of the year at the geographical place where the mixing device is to be used.

#### **Textual Amendments**

- F9 Inserted by Commission Regulation (EU) No 749/2011 of 29 July 2011 amending Regulation (EU) No 142/2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (Text with EEA relevance).
- J. Multi-step catalytic process for the production of renewable fuels
- 1. Starting materials
- (a) For this process, the following materials may be used:
- (i) rendered fats derived from Category 2 material, which have been processed using processing method 1 (pressure sterilisation);
- (ii) fish oil or rendered fats derived from Category 3 material, which have been processed using:
  - any of the processing methods 1 to 5 or processing method 7; or
  - in the case of material derived from fish oil, any of the processing methods 1 to 7;
- (iii) fish oil or rendered fat which have been produced in accordance with Sections VIII or XII of Annex III to Regulation (EC) No 853/2004, respectively.
- (b) The use of rendered fats derived from Category 1 material for this process shall be prohibited.
- 2. Processing method
- (a) The rendered fat must be submitted to a pre-treatment which consists of:
- (i) the bleaching of the centrifuged materials by passing them through a clay filter;
- (ii) the removal of remaining insoluble impurities by filtration.
- (b) The pre-treated materials must be submitted to a multi-step catalytic process which consists of a hydro-deoxygenisation step, followed by an isomerisation step.

The materials must be submitted to a pressure of at least 20 bars at a temperature of at least 250 °C for at least 20 minutes.]

- $I^{F4}K$ . Ensilage of fish material
- 1. Starting materials

For this process, only the following by-products obtained from aquatic animals may be used:

- (a) Category 2 materials referred to in Article 9(f)(i) and (iii) of Regulation (EC) No 1069/2009;
- (b) Category 3 materials.
- 2. Processing method
- 2.1. The materials to be treated shall be collected at aquaculture farms and food processing establishments on a daily basis and without undue delays, ground or chopped, and thereafter subjected to ensiling at a pH of 4 or below, with formic acid or other organic acid authorised in accordance with the feed legislation. The resulting fish silage must be a suspension of parts of aquatic animals liquefied by the action of endogenous enzymes in the presence of the added acid. The proteins of aquatic animals must be reduced into smaller soluble units, by the enzymes and the acid, in order to prevent microbial spoilage. The ensiled material is transported to the processing plant.
- 2.2. At the processing plant the ensiled material of aquatic animals must be piped into closed storage tanks. The incubation time must be at least 24 hours at a pH of 4 or below before heat treatment can be conducted. Before the heat treatment the ensilage of aquatic animals must have a pH of 4 or below and have a particle size of less than 10 mm following a filtration or maceration at the plant. During processing it must be subjected to preheating to a temperature above 85 °C, followed by incubation in an insulated container to obtain 85 °C throughout the fish material for 25 minutes. The process must take place in a closed production line with tanks and pipelines.
- 2.3. Before authorisation is given, the operator's permanent written procedure referred to in Article 29(1) to (3) of Regulation (EC) No 1069/2009 must be assessed by the competent authority.]

# Section 3

# Disposal and use of derived products

- 1. Products derived from the processing of:
- (a) Category 1 material shall be:
  - (i) disposed of in accordance with Article 12(a) or (b) of Regulation (EC) No 1069/2009;
  - (ii) disposed of by burial in an authorised landfill;
  - (iii) [<sup>F1</sup>transformed into biogas. In such case the digestion residues must be disposed of in accordance with point (i) or (ii), except where the material results from processing in accordance with point 2(a) or (b) where the residues can be used in accordance with the conditions set out in point 2(a) or point 2(b)(iii) as appropriate; or]
  - (iv) further processed into fat derivatives for uses other than feeding.

- (b) Category 2 or Category 3 material shall be:
  - (i) [<sup>F1</sup>disposed of as provided for in point 1(a)(i) or (ii), with or without prior processing as provided for in Article 13(a) and (b) and Article 14(a) and (b) of Regulation (EC) No 1069/2009;]
  - (ii) further processed into fat derivatives for uses other than feeding;
  - (iii) used as an organic fertiliser or soil improver; or
  - (iv) composted or transformed into biogas.
- 2. Materials resulting from processing in accordance with:
- (a) the alkaline hydrolysis process defined in point A of Section 2 may be transformed in a biogas plant and subsequently combusted rapidly at a minimum of 900 °C, followed by rapid chilling ('quenching'); where material referred to in Article 8(a) and (b) of Regulation (EC) No 1069/2009 has been used as starting material, the transformation into biogas shall take place on the same site as the processing and in a closed system;
- (b) the biodiesel production process may be:
  - (i) in the case of biodiesel and of residues from the distillation of biodiesel, used as a fuel without restrictions under this Regulation (end point);
  - (ii) [<sup>F1</sup>in the case of potassium sulphate, used for direct application to land or for the production of derived products for application to land;
  - (iii) in the case of glycerine derived from Categories 1 and 2 material which has been processed in accordance with processing method 1 as set out in Chapter III:
    - used for technical purposes,
    - transformed into biogas, in which case the digestion residues may be applied to land within the national territory of the producing Member State, subject to the decision of the competent authority, or
    - used for denitrification in a waste water treatment plant, in which case the residues of the denitrification may be applied to land in accordance with Council Directive 91/271/EEC<sup>(3)</sup>;
  - (iv) in the case of glycerine derived from Category 3 material:
    - used for technical purposes,
    - transformed into biogas, in which case the digestion residues may be applied to land, or
    - used for feeding, provided that the glycerine is not derived from Category 3 material referred to in Article 10(n), (o) and (p) of Regulation (EC) No 1069/2009;]
- (c) [<sup>F9</sup>the multi-step catalytic process for the production of renewable fuels may be:
  - (i) in the case of gasoline and the other fuels resulting from the process, used as a fuel without restrictions under this Regulation (end point);
  - (ii) in the case of used clay from bleaching and sludge from the pre-treatment process referred to in point J(2)(a) of Section 2:
    - disposed of by incineration or co-incineration,

- transformed into biogas,
- composted or used for the manufacture of derived products referred to in Article 36(a)(i) of Regulation (EC) No 1069/2009;]
- (d) [<sup>F3</sup>the lime-treated mixture of pig and poultry manure may be applied to land as processed manure;]
- (e) [<sup>F4</sup>The final product derived from the ensilaging of fish material may:
  - (i) for Category 2 materials, be used for purposes referred to in Article 13(a) to (d) and (g) to (i) of Regulation (EC) No 1069/2009 without further processing or as feed for animals referred to in Article 18 or Article 36(a) (ii) of that Regulation; or
  - (ii) for Category 3 materials, be used for purposes referred to in Article 14 of Regulation (EC) No 1069/2009.]
- [<sup>F1</sup>3. Any waste other than animal by-products and derived products provided for in point 2, resulting from the processing of animal by-products in accordance with this Section, such as sludge, filter contents, ash and digestion residues, shall be disposed of in accordance with Regulation (EC) No 1069/2009 and with this Regulation.]

# ANNEX V

# TRANSFORMATION OF ANIMAL BY-PRODUCTS AND DERIVED PRODUCTS INTO BIOGAS, COMPOSTING

# CHAPTER I

# **REQUIREMENTS APPLICABLE TO PLANTS**

# Section 1

#### **Biogas plants**

- 1. A biogas plant must be equipped with a pasteurisation/hygienisation unit, which cannot be by-passed for the animal by-products or derived products introduced with a maximum particle size of 12 mm before entering the unit, with:
- (a) installations for monitoring that the temperature of 70 °C is reached during the time of one hour;
- (b) recording devices to record continuously the results of the monitoring measurements referred to in point (a); and
- (c) an adequate system to prevent insufficient heating.
- 2. By way of derogation from point 1, a pasteurisation /hygienisation unit shall not be mandatory for biogas plants that transform only:
- (a) Category 2 material that has been processed in accordance with processing method 1 as set out in Chapter III of Annex IV;

- (b) Category 3 material that has been processed in accordance with any of the processing methods 1 to 5 or processing method 7, or in the case of material originating from aquatic animals, any of the processing methods 1 to 7, as set out in Chapter III of Annex IV;
- (c) Category 3 material that has undergone pasteurisation/hygienisation in another approved plant;
- (d) [<sup>F1</sup>animal by-products which may be applied to land without processing in accordance with Article 13(f) of Regulation (EC) No 1069/2009 and with this Regulation, if the competent authority does not consider them to present a risk of spreading any serious transmissible disease to humans or animals;]
- (e) animal by-products which have been subject to the alkaline hydrolysis process set out in point A of Section 2 of Chapter IV of Annex IV;
- (f) the following animal by-products, if authorised by the competent authority:
  - the animal by-products referred to in Article 10(f) of Regulation (EC) No 1069/2009, which have undergone processing as defined in Article 2(1)(m) of Regulation (EC) No 852/2004 at the time when they are destined for purposes other than human consumption;
  - (ii) the animal by-products referred to in Article 10(g) of Regulation (EC) No 1069/2009; or
  - (iii) animal by-products which are transformed into biogas, where the digestion residues are subsequently composted or processed or disposed of in accordance with this Regulation.
- 3. If the biogas plant is located on or next to premises where farmed animals are kept and the biogas plant does not only use manure, milk or colostrum which accrues from those animals, the plant shall be located at a distance from the area where such animals are kept.

That distance shall be determined in a manner which ensures that there is no unacceptable risk for the transmission of a disease communicable to humans or animals from the biogas plant.

In all cases, there must be total physical separation between that biogas plant and the animals and their feed and bedding, with fencing where necessary.

4. Each biogas plant must have its own laboratory or make use of an external laboratory. The laboratory must be equipped to carry out necessary analyses and be approved by the competent authority, be accredited according to internationally recognised standards or be subject to regular controls by the competent authority.

# Section 2

# **Composting plants**

- 1. A composting plant must be equipped with a closed composting reactor or closed area, which cannot be by-passed for the animal by-products or derived products introduced into the plant, and it must be equipped with the following:
- (a) installations for monitoring temperature against time;

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- (b) recording devices to record, where appropriate continuously, the results of the monitoring measurements referred to in point (a);
- (c) an adequate safety system to prevent insufficient heating.
- 2. By way of derogation from point 1, other types of composting systems may be allowed provided they:
- (a) are managed in such a way that all the material in the system achieves the required time and temperature parameters, including, where appropriate, continuous monitoring of the parameters; or
- (b) transform only materials referred to in point 2 of Section 1; and
- (c) comply with all other relevant requirements of this Regulation.
- 3. If the composting plant is located on or next to premises where farmed animals are kept and the composting plant does not only use manure, milk or colostrum which accrues from those animals, the composting plant shall be located at a distance from the area where animals are kept.

That distance shall be determined in a manner which ensures that there is no unacceptable risk for the transmission of a disease communicable to humans or animals from the composting plant.

In all cases, there must be total physical separation between that composting plant and the animals and their feed and bedding, with fencing where necessary.

4. Each composting plant must have its own laboratory or make use of an external laboratory. The laboratory must be equipped to carry out necessary analyses and be approved by the competent authority, be accredited according to internationally recognised standards or be subject to regular controls by the competent authority.

# CHAPTER II

#### HYGIENE REQUIREMENTS APPLICABLE TO BIOGAS AND COMPOSTING PLANTS

- 1. Animal by-products must be transformed as soon as possible after arrival at the biogas or composting plant. They must be stored properly until treated.
- 2. Containers, receptacles and vehicles used for transporting untreated material must be cleaned and disinfected in a designated area.

That area must be situated or designed so as to prevent risk of contamination of treated products.

3. Preventive measures against birds, rodents, insects or other vermin must be taken systematically.

A documented pest-control programme must be used for that purpose.

- 4. Cleaning procedures must be documented and established for all parts of the premises. Suitable equipment and cleaning agents must be provided for cleaning.
- 5. Hygiene control must include regular inspections of the environment and equipment. Inspection schedules and results must be documented.

- 6. Installations and equipment must be kept in a good state of repair and measuring equipment must be calibrated at regular intervals.
- 7. Digestion residues and compost must be handled and stored at the biogas or composting plant in such way as to prevent recontamination.

# CHAPTER III

# TRANSFORMATION PARAMETERS

# Section 1

#### **Standard transformation parameters**

- 1. Category 3 material which is used as raw material in a biogas plant equipped with a pasteurisation/hygienisation unit must be submitted to the following minimum requirements:
- (a) maximum particle size before entering the unit: 12 mm;
- (b) minimum temperature in all material in the unit: 70 °C; and
- (c) minimum time in the unit without interruption: 60 minutes.

However, Category 3 milk, milk-based products, milk-derived products, colostrum and colostrum products may be used without pasteurisation/hygienisation as raw material in a biogas plant, if the competent authority does not consider them to present a risk of spreading any serious transmissible disease to humans or animals.

The minimum requirements set out in points (b) and (c) of this point shall also apply to Category 2 material which is introduced into a biogas plant without prior processing in accordance with Article 13(e)(ii) of Regulation (EC) No 1069/2009.

- 2. Category 3 material which is used as raw material in a composting plant must be submitted to the following minimum requirements:
- (a) maximum particle size before entering the composting reactor: 12 mm;
- (b) minimum temperature in all material in the reactor: 70 °C; and
- (c) minimum time without interruption: 60 minutes.

The minimum requirements set out in points (b) and (c) of this point shall also apply to Category 2 material which is composted without prior processing in accordance with Article 13(e)(ii) of Regulation (EC) No 1069/2009.

# Section 2

#### Alternative transformation parameters for biogas and composting plant

1. The competent authority may authorise the use of parameters other than the parameters set out in point 1 of Section 1 of Chapter I and other than the standard transformation parameters, provided that the applicant for such use demonstrates that such parameters

ensure adequate reduction of biological risks. That demonstration shall include a validation, which shall be carried out in accordance with the following requirements:

- (a) Identification and analysis of possible hazards, including the impact of input material, based on a full description of the transformation conditions and parameters;
- (b) A risk assessment, which evaluates how the specific transformation conditions referred to in point (a) are achieved in practice under normal and atypical situations;
- (c) Validation of the intended process by measuring the reduction of viability/infectivity of:
  - (i) endogenous indicator organisms during the process, where the indicator is:
    - consistently present in the raw material in high numbers,
      - not less heat resistant to the lethal aspects of the transformation process, but also not significantly more resistant than the pathogens for which it is being used to monitor,
      - relatively easy to quantify and to identify and to confirm; or
  - (ii) a well-characterised test organism or virus, during exposure, introduced in a suitable test body into the starting material.
- (d) The validation of the intended process referred to in point (c) must demonstrate that the process achieves the following overall risk reduction:
  - (i) for thermal and chemical processes by:
    - a reduction of 5 log10 of *Enterococcus faecalis* or *Salmonella Senftenberg* (775W, H2S negative),
    - reduction of infectivity titre of thermoresistant viruses such as parvovirus by at least 3 log10, whenever they are identified as a relevant hazard; and
  - (ii) as regards chemical processes also by:
    - a reduction of resistant parasites such as eggs of *Ascaris* sp. by at least 99,9 % (3 log10) of viable stages;
- (e) Designing a complete control programme including procedures for monitoring the functioning of the process referred to in point (c);
- (f) Measures ensuring continuous monitoring and supervision of the relevant process parameters fixed in the control programme when operating the plant.

Details on the relevant process parameters used in a biogas or composting plant as well as other critical control points must be recorded and maintained so that the owner, operator or their representative and the competent authority can monitor the operation of the plant.

Records must be made available by the operator to the competent authority on request. Information relating to a process authorised under this point must be made available to the Commission on request.

2. By way of derogation from point 1, pending the adoption of rules as referred to in Article 15(2)(a)(ii) of Regulation (EC) No 1069/2009, the competent authority may authorise the use of specific requirements other than those laid down in this Chapter, provided that they guarantee an equivalent effect regarding the reduction of pathogens, for:

- (a) catering waste used as the only animal by-product in a biogas or composting plant; and
- (b) mixtures of catering waste with the following materials:
  - (i) manure;
  - (ii) digestive tract content separated from the digestive tract;
  - (iii) milk;
  - (iv) milk-based products;
  - (v) milk-derived products;
  - (vi) colostrum;
  - (vii) colostrum products;
  - (viii) eggs;
  - (ix) egg products;
  - (x) [<sup>F3</sup>animal by-products referred to in Article 10(f) of Regulation (EC) No 1069/2009, which have undergone processing as defined in Article 2(1)(m) of Regulation (EC) No 852/2004;]
  - (xi) [<sup>F4</sup>mixture of animal by-products referred to in point 2(b) with non-animal by-product materials.]
- 3. Where the materials referred to in point 2(b) or derived products referred to in Article 10(g) of Regulation (EC) No 1069/2009 are the only starting material of animal origin being treated in a biogas or composting plant, the competent authority may authorise the use of specific requirements other than those specified in this Chapter provided that it:
- (a) does not consider that those materials present a risk of spreading any serious transmissible disease to humans or animals;
- (b) [<sup>F3</sup>considers that the digestion residues or compost are unprocessed material and obliges operators to handle them in accordance with Regulation (EC) No 1069/2009, with this Regulation or, in the case of compost or digestion residues derived from catering waste, to recover or dispose of in accordance with the environmental legislation.]
- 4. Operators may place on the market digestion residues and compost, which have been produced according to parameters which have been authorised by the competent authority:
- (a) in accordance with point 1;
- (b) in accordance with points 2 and 3, only within the Member State where those parameters have been authorised.

# Section 3

#### Standards for digestion residues and compost

1.

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(a) Representative samples of the digestion residues or compost taken during or immediately after transformation at the biogas plant or composting at the composting plant in order to monitor the process must comply with the following standards:

*Escherichia coli*: n = 5, c = 1, m = 1 000, M = 5 000 in 1 g;

or

Enterococcaceae: n = 5, c = 1,  $m = 1\ 000$ ,  $M = 5\ 000$  in 1 g;

and

(b) Representative samples of the digestion residues or compost taken during or on withdrawal from storage must comply with the following standards:

Salmonella: absence in 25 g: n = 5; c = 0; m = 0; M = 0

Where in the case of point (a) or (b):

- n = number of samples to be tested;
- m = threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria in all samples does not exceed m;
- M = maximum value for the number of bacteria; the result is considered unsatisfactory if the number of bacteria in one or more samples is M or more; and
  - number of samples the bacterial count of which may be between m and M, the sample still being considered acceptable if the bacterial count of the other samples is m or less.
- 2. Digestion residues or compost, which do not comply with the requirements set out in this Section, shall be resubmitted to transformation or composting, and in the case of Salmonella handled or disposed of in accordance with the instructions of the competent authority.
- [<sup>F9</sup>3. When animal by-products are transformed into biogas or composted together with materials which are not of animal origin, the competent authority may authorise operators to take representative samples after the pasteurisation referred to in point 1(a) of Section 1 of Chapter I or after composting referred to in point 1 of Section 2, as applicable, and before the mixing with materials which are not of animal origin takes place, in order to monitor the efficiency of the transformation or composting of the animal by-products, as applicable.]

с

#### ANNEX VI

#### SPECIAL RULES ON RESEARCH, FEEDING AND COLLECTION AND DISPOSAL

### CHAPTER I

#### SPECIAL RULES ON SAMPLES FOR RESEARCH AND OTHER PURPOSES

#### Section 1

#### **Research and diagnostic samples**

- 1. Operators shall ensure that consignments of research and diagnostic samples are accompanied by a commercial document, which must specify:
- (a) the description of the material and the animal species of origin;
- (b) the category of the material;
- (c) the quantity of the material;
- (d) the place of origin and the place of dispatch of the material;
- (e) the name and the address of the consignor;
- (f) the name and the address of the consignee and/or user.
- 2. Users that handle research and diagnostic samples shall take all necessary measures to avoid the spreading of diseases communicable to humans or animals during the handling of the materials under their control, in particular by way of the application of good laboratory practice.
- 3. Any subsequent use of research and diagnostic samples for purposes other than those referred to in point 38 of Annex I shall be prohibited.
- 4. Unless they are kept for reference purposes, research and diagnostic samples and any products derived from the use of those samples shall be disposed of:
- (a) as waste by incineration or co-incineration;
- (b) in case of the animal by-products or derived products referred to in Article 8 (a)(iv), Article 8(c) and (d) and Article 9 and Article 10 of Regulation (EC) No 1069/2009 which are part of cell cultures, laboratory kits or laboratory samples, by a treatment under conditions which are at least equivalent to the validated method for steam autoclaves<sup>(4)</sup> and subsequent disposal as waste or wastewater in accordance with relevant Union legislation;
- (c) by pressure sterilisation and subsequent disposal or use in accordance with Articles 12, 13 and 14 of Regulation (EC) No 1069/2009.
- 5. Users that handle research and diagnostic samples shall keep a register of consignments of such samples.

The register shall include the information referred to in point 1 and the date and method of disposal of the samples and of any derived products.

6. By way of derogation from points 1, 4 and 5, the competent authority may accept the handling and disposal of research and diagnostic samples for educational purposes under other conditions which ensure that no unacceptable risks for public or animal health arise.

#### Section 2

#### Trade samples and display items

- 1. Trade samples and display items may only be transported, used and disposed of in accordance with points 1 to 4 and 6 of Section 1.
- 2. Unless trade samples are kept for reference purposes, they shall be, after the particular studies or analyses have been concluded:
- (a) redispatched to the Member State of origin;
- (b) dispatched to another Member State or third country, if such dispatch has been authorised by the competent authority of the Member State or third country of destination in advance; or
- (c) disposed of or used in accordance with Articles 12, 13 and 14 of Regulation (EC) No 1069/2009.
- 3. After the exhibition or after the artistic activity has been concluded, display items shall be redispatched to the Member State of origin, dispatched or disposed of, in accordance with point 2.

# CHAPTER II

#### **SPECIAL FEEDING RULES**

#### Section 1

# **General requirements**

[<sup>F1</sup>Categories 2 and 3 materials as referred to in Article 18(1) of Regulation (EC) No 1069/2009 may be fed to the animals referred to in paragraph (1)(a), (b), (d), (f), (g) and (h) of that Article subject to compliance with at least the following conditions, in addition to any conditions laid down by the competent authority in accordance with Article 18(1) of that Regulation:]

- 1. The animal by-products shall be transported to the users or to collection centres in accordance with Sections 1 and 3 of Chapter I of Annex VIII.
- 2. Collection centres shall be registered by the competent authority, provided that:
  - (a) they comply with the requirements for plants carrying out the intermediate operations set out in Chapter II of Annex IX; and
  - (b) they have adequate facilities for destroying unused material, or send it to an approved processing plant or to an approved incineration or co-incineration plant in accordance with this Regulation.

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- 3. Member States may authorise the use of a processing plant for Category 2 material as a collection centre.
- 4. Operators of collection centres supplying material, other than animal by-products originating from aquatic animals and from aquatic invertebrates, to final users must ensure that it undergoes one of the following treatments:
  - (a) denaturing with a solution of a colouring agent; the solution must be of such a strength that the colouring on the stained material is clearly visible and does not disappear when the coloured materials are subject to freezing or chilling, and the whole surface of all pieces of material must have been covered with such solution either by immersing the material in, or spraying or otherwise applying the solution;
  - (b) sterilisation by boiling or steaming under pressure until every piece of material is cooked throughout; or
  - (c) any other handling or treatment authorised by the competent authority responsible for the operator.

# Section 2

# Feeding of certain species in feeding stations

- 1. The competent authority may authorise the use of Category 1 material referred to in Article 18(2)(b) of Regulation (EC) No 1069/2009 for the feeding of the following endangered and protected species in feeding stations under the following conditions:
- (a) The material must be fed to:
  - (i) [<sup>F3</sup>one of the following species of necrophagous birds in the following Member States:

Country code	Member State	Animal species	
		Local name	Latin name
BG	Bulgaria	bearded vulture black vulture Egyptian vulture griffon vulture golden eagle imperial eagle white-tailed eagle black kite red kite	Gypaetus barbatus Aegypius monachus Neophron percnopterus Gyps fulvus Aquila chrysaetos Aquila helíaca Haliaeetus albicilla Milvus migrans Milvus milvus
EL	Greece	bearded vulture black vulture Egyptian vulture griffon vulture	Gypaetus barbatus Aegypius monachus

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golden eagle Neophron imperial eagle percnopterus white-tailed *Gyps fulvus* eagle Aquila black kite chrysaetos Aquila heliaca Haliaeetus albicilla Milvus migrans ES bearded vulture Spain *Gypaetus* barbatus black vulture Egyptian vulture Aegypius griffon vulture monachus golden eagle Neophron Spanish imperial percnopterus eagle Gyps fulvus black kite Aquila red kite chrysaetos *Aquila adalberti* Milvus migrans Milvus milvus FR France bearded vulture *Gypaetus* black vulture barbatus Egyptian vulture Aegypius griffon vulture monachus golden eagle Neophron white-tailed percnopterus eagle Gyps fulvus black kite Aquila red kite chrysaetos Haliaeetus albicilla Milvus migrans Milvus milvus HR Croatia bearded vulture Gypaetus black vulture barbatus Egyptian vulture Aegypius griffon vulture monachus Neophron percnopterus *Gyps fulvus* IT bearded vulture Gypaetus Italy black vulture barbatus Egyptian vulture Aegypius griffon vulture monachus golden eagle Neophron black kite percnopterus red kite Gyps fulvus Aquila chrysaetos Milvus migrans

			Milvus milvus
СҮ	Cyprus	black vulture griffon vulture	Aegypius monachus Gyps fulvus
PT	Portugal	black vulture Egyptian vulture griffon vulture golden eagle	Aegypius monachus Neophron percnopterus Gyps fulvus Aquila chrysaetos
SK	Slovakia	golden eagle imperial eagle white-tailed eagle black kite red kite	Aquila chrysaetos Aquila heliaca Haliaeetus albicilla Milvus migrans Milvus milvus]

- (ii) one of the species of the order Carnivora which are listed in Annex II to Directive 92/43/EEC, in special areas of conservation which have been set up under that Directive; or
- (iii) one of the species of the orders Falconiformes or Strigiformes, which are listed in Annex I to Directive 2009/147/EC, in special protection areas which have been set up under that Directive;
- (b) The competent authority has granted an authorisation to the operator responsible for the feeding station.

The competent authority shall grant such authorisations provided that:

- (i) the feeding is not used as an alternative way of disposal of specified risk materials or the disposal of fallen ruminant stock containing such material posing a TSE risk;
- (ii) an appropriate surveillance system for TSEs as laid down in Regulation (EC) No 999/2001 is in place involving regular laboratory testing of samples for TSE;
- (c) The competent authority must ensure coordination with any other competent authorities responsible for the supervision of the requirements laid down in the authorisation;
- (d) The competent authority must be satisfied, on the basis of an assessment of the specific situation of the species concerned and their habitat, that the conservation status of the species will be improved;
- (e) The authorisation granted by the competent authority must:
  - (i) refer to and name the species actually concerned;
  - (ii) describe in detail the location of the feeding station in the geographical area where feeding shall take place; and

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- (iii) be immediately suspended in the case of:
  - a suspected or confirmed link to the spread of TSE until the risk can be excluded, or
  - non-compliance with any of the rules provided for in this Regulation.

(f) The operator responsible for the feeding shall:

- (i) dedicate an area to the feeding that is enclosed and to which access is limited to animals of the species to be conserved, if appropriate by fences or by other means which correspond to the natural feeding patterns of those species;
- (ii) ensure that eligible bodies of bovine animals and at least 4 % of eligible bodies of ovine and caprine animals intended to be used for feeding are tested prior to that use with a negative result, in the TSE monitoring programme carried out in accordance with Annex III to Regulation (EC) No 999/2001 and, if applicable, in accordance with a Decision adopted in accordance with the second subparagraph of Article 6(1b) of that Regulation; and
- (iii) keep records at least of the number, nature, estimated weight and origin of the carcases of the animals used for feeding, the date of the feeding, the location where feeding took place and if applicable, the results of the TSE tests.
- 2. When a Member State applies to the Commission to be included into the list set out under point 1(a), it shall submit:
- (a) a detailed justification for the extension of the list to include certain species of necrophagous birds in that Member State, including an explanation of the reasons why it is necessary to feed such birds with Category 1 material instead of with Category 2 or Category 3 material;
- (b) an explanation of the measures which will be taken in order to ensure compliance with point 1.

# Section 3

# Feeding of wild animals outside feeding stations

The competent authority may authorise the use of Category 1 material comprising of entire bodies or parts of dead animals containing specified risk materials outside feeding stations, if appropriate without prior collection of the dead animals, for feeding to wild animals referred to in point 1(a) of Section 2 under the following conditions:

- 1. The competent authority must be satisfied, on the basis of an assessment of the specific situation of the species concerned and their habitat, that the conservation status of the species will be improved;
- 2. The competent authority must identify in the authorisation, holdings or herds within a geographically defined feeding zone under the following conditions:
  - (a) The feeding zone must not extend to areas where intensive farming of animals takes place;

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(b)	Farmed animals in holdings or herds in the feeding zone must be under the regular surveillance of an official veterinarian regarding the prevalence of TSE and of diseases transmissible to humans or animals;		
(c)	Feeding must be immediately suspended in the case of:		
	(i)	a suspected or confirmed link to the spread of TSE in a holding or herd, until the risk can be excluded;	
	(ii)	a suspected or confirmed outbreak of a serious disease transmissible to humans or animals in a holding or herd, until the risk can be excluded; or	
	(iii)	non-compliance with any of the rules provided for in this Regulation;	
(d)	The competent authority must specify in the authorisation:		
	(i)	appropriate measures to prevent the transmission of TSE and of transmissible diseases from the dead animals to humans or other animals, such as measures targeted at the feeding patterns of the species to be conserved, seasonal feeding restrictions, movement restrictions for farmed animals and other measures intended to control possible risks of transmission of a disease communicable to humans or animals, such as measures relating to species present in the feeding zone for the feeding of which the animal by-products are not used;	
	(ii)	the responsibilities of persons or entities in the feeding zone who are assisting with the feeding or responsible for farmed animals, in relation to the measures referred to under point (i);	
	(iii)	the conditions for the imposition of penalties as referred to in Article 53 of Regulation (EC) No 1069/2009 which are applicable to infringements of measures referred to under point (i) by the persons or entities referred to under point (ii) of this point (d);	

(e) Where the feeding is carried out without the prior collection of the dead animals, an estimate of the likely mortality rate of farmed animals in the feeding zone and of the likely feeding requirements of the wild animals must be carried out, as a basis for the assessment of the potential risks of disease transmission.

#### Section 4

### Feeding of zoo animals with Category 1 material

The competent authority may authorise the use of Category 1 material comprising of entire bodies or parts of dead animals containing specified risk materials and the use of material derived from zoo animals, for the feeding of zoo animals under the following conditions:

(a) The competent authority must have granted an authorisation to the operator responsible for the feeding. The competent authority shall grant such authorisations provided that:

- (i) the feeding is not used as an alternative way of disposal of specified risk materials or disposal of fallen ruminant stock containing such material posing a TSE risk;
- (ii) when Category 1 material comprising of entire bodies or parts of dead animals containing specified risk material, which originates from bovine animals is used, an appropriate surveillance system for TSEs as laid down in Regulation (EC) No 999/2001 is in place involving regular laboratory testing of samples for TSEs;
- (b) The authorisation granted by the competent authority must be immediately suspended in the case of:
  - (i) a suspected or confirmed link to the spread of TSEs until the risk can be excluded; or
  - (ii) non-compliance with any of the rules provided for in this Regulation;
- (c) The operator responsible for the feeding shall:
  - (i) store the material to be used for the feeding and carry out the feeding in an enclosed and fenced area to ensure that no carnivorous animal other than the zoo animals for which the authorisation has been granted have access to the material for the feeding;
  - (ii) ensure that ruminant animals intended to be used for feeding are included in the TSE monitoring programme carried out in accordance with Annex III to Regulation (EC) No 999/2001 and, if applicable, in accordance with a Decision adopted in accordance with the second subparagraph of Article 6(1b) of that Regulation;
  - (iii) keep records at least of the number, nature, estimated weight and origin of the bodies of the animals used for feeding, the results of the TSE tests and the date of the feeding.

# CHAPTER III

# SPECIAL RULES ON COLLECTION AND DISPOSAL

# Section 1

# Special disposal rules for animal by-products

- 1. If the competent authority authorises the disposal of animal by-products on site in accordance with Article 19(1)(a), (b), (c) and (e) of Regulation (EC) No 1069/2009, such disposal may take place:
- (a) by burning or burial on the premises on which the animal by-products originate;
- (b) in an authorised landfill; or
- (c) by burning or burial at a site which minimises the risk to animal and public health and the environment, provided that the site is located within a range of distance sufficient

to enable the competent authority to manage the prevention of the risk to animal and public health and the environment.

- 2. The burning of animal by-products on the sites referred to in Article 19(1)(b), (c) and (e) of Regulation (EC) No 1069/2009 must be carried out in such a way to ensure that they are burnt:
- (a) on a properly constructed pyre and the animal by-products reduced to ash;
- (b) without endangering human health;
- (c) without using processes or methods which could harm the environment, in particular when they could result in risks to water, air, soil and plants and animals or through noise or odours;
- (d) under conditions which ensure that any resulting ash is disposed of by burial in an authorised landfill.
- 3. The burial of animal by-products on the sites referred to in Article 19(1)(a), (b), (c) and (e) of Regulation (EC) No 1069/2009 must be carried out to ensure that they are buried:
- (a) in such a way that carnivorous or omnivorous animals cannot gain access to them;
- (b) in an authorised landfill or in another site without endangering human health and using processes or methods which do not harm the environment, in particular when they could result in risks to water, air, soil and plants and animals, or through noise or odours.
- 4. In the case of disposal in accordance with Article 19(1)(a), (b), (c) and (e) of Regulation (EC) No 1069/2009, the movement of the animal by-products from the place of origin to the place of disposal must be carried out under the following conditions:
- (a) the animal by-products are transported in secure, leak-proof containers or vehicles;
- (b) the loading and unloading of the animal by-products is supervised by the competent authority, if appropriate;
- (c) the vehicle wheels are disinfected upon leaving the site of origin;
- (d) containers and vehicles used for transporting animal by-products are thoroughly cleansed and disinfected after unloading of the animal by-products; and
- (e) adequate escorts for the vehicles, leak testing and double covering are provided, if appropriate.

# Section 2

#### Burning and burial of animal by-products in remote areas

The maximum percentage as referred to in Article 19(2) of Regulation (EC) No 1069/2009 shall not exceed the following:

- (a) 10 % of the bovine population of the Member State concerned;
- (b) 25 % of the ovine and caprine population of the Member State concerned;

- (c) 10 % of the porcine population of the Member State concerned; and
- (d) a percentage of the population of other species which is determined by the competent authority, on the basis of an assessment of the possible risks for public and animal health which arise from the disposal of animals of those species by burning or burial on site.

#### Section 3

# Burning and burial of bees and apiculture by-products

In the case of bees and apiculture by-products, the competent authority may authorise the disposal by burning or burial on site, as referred to in Article 19(1)(f) of Regulation (EC) No 1069/2009, provided that all necessary measures are taken to ensure that the burning or burial does not endanger animal or human health or the environment.

# CHAPTER IV

# **DISPOSAL BY OTHER MEANS**

By way of derogation from Article 14 of Regulation (EC) No 1069/2009, Member States may authorise the collection, transport and disposal of the Category 3 materials referred to in Article 10(f) of that Regulation by means other than burning or burial on site provided that:

- (a) the materials do not exceed a volume of 20 kg per week from the establishment or plant where the materials are collected, regardless of the species of origin of the materials;
- (b) the materials are collected, transported and disposed of by means which prevent the transmission of unacceptable risks to public and animal health;
- (c) the competent authority carries out regular checks, including checks on the records kept by operators, in the establishments or plants where the materials are collected, to ensure compliance with the provisions of this Section.

[<sup>F8</sup>.....]

# ANNEX VII

# STANDARD FORMAT FOR APPLICATIONS FOR ALTERNATIVE METHODS

# CHAPTER I

#### Language regime

1. Applications for authorisation of an alternative method of use or disposal of animal by-products or derived products as referred to in Article 20 of Regulation (EC) No 1069/2009 (applications) shall be submitted in one of the official languages of the European Union as referred to in Article 1 of Regulation No 1 of 1958.

2. Interested parties that submit such applications in a language other than English shall validate the official translation of their application, which EFSA shall provide, prior to the assessment.

The period referred to in Article 20(5) of Regulation (EC) No 1069/2009 shall only start once the interested party has validated the official translation of the application.

# CHAPTER II

### **Content of applications**

- [<sup>F5</sup>1. Applications shall contain all the necessary information to allow EFSA to assess the safety of the proposed alternative method, and in particular describe:
- the categories of animal by-products intended to be submitted to the method,
- the entire process,
- the biological hazards for human and animal health involved, and
- the degree of risk reduction to be achieved by the process.
- 2. The application referred to in paragraph 1 shall moreover:
- (a) indicate the applicable points in Articles 8, 9 and 10 of Regulation (EC) No 1069/2009 including the physical status of those materials and, if applicable, any pre-treatment to which those materials have been submitted and indicating any materials other than animal by-products which are to be used in the process.
- (b) include a HACCP protocol and a flow diagram which clearly indicates the individual steps of the process, identifies the parameters critical for the inactivation of relevant pathogens such as temperature, pressure, exposure time, adjustment of the pH value and particle size and is complemented by technical data sheets of the equipment used during the process;
- (c) identify and characterize biological hazards for human and animal health represented by the categories of animal by-products intended to be submitted to the method;
- (d) show that the most resistant biological hazards associated with the category of materials to be processed are reduced in any products generated during the process, including the waste water, at least to the degree achieved by the processing standards laid down in this Regulation for the same category of animal by-products. The degree of risk reduction must be determined with validated direct measurements, unless modelling or comparisons with other processes are acceptable.
- 3. Validated direct measurements as referred to in paragraph 2(d) above shall mean:
- (a) measuring the reduction of viability/infectivity of: endogenous indicator organisms during the process, where the indicator is:
  - consistently present in the raw material in high numbers;
  - not less resistant to the lethal aspects of the treatment process, but also not significantly more resistant than the pathogens for which it is being used to monitor;
  - relatively easy to quantify, to identify and to confirm; or
- (b) using a well-characterised test organism or virus introduced in a suitable test body into the starting material.

If several treatment steps are involved, an assessment must be performed on the degree to which individual titre reduction steps are additive, or whether early steps in the process may compromise the efficacy of subsequent steps;

- (c) reporting complete results by
  - (i) describing in detail the used methodology;
  - (ii) describing the nature of samples which have been analysed;
  - (iii) showing that the number of samples analysed is representative;
  - (iv) justifying the number of tests performed and the selection of measuring points;
  - (v) indicating the sensitivity and the specificity of the detection methods used;
  - (vi) providing data on the repeatability and statistical variability of the measurements obtained during the experiments;
  - (vii) justifying, if used the significance of prion surrogates;
  - (viii) showing, where in absence of direct measurements, models or comparisons with other processes are used, that the factors leading to risk reduction are well known and the model of risk reduction is well established;
  - (ix) providing data for the entire process on direct measurements of all factors leading to the risk reduction which demonstrate that these factors are homogenously applied throughout the treated batch.
- 4. The HACCP plan referred to in paragraph 2(b) must be based on the critical parameters which are used to obtain the risk reduction, in particular:
- temperature,
- pressure,
- time, and
- microbiological criteria.

The critical limits retained in the HACCP plan must be defined, based on the results of the experimental validation and/ or of the model provided.

If the successful functioning of the process can only be demonstrated with reference to technical parameters which are specifically related to the equipment used in the process, the HACCP plan must also include the technical limits which must be met, in particular energy uptake, number of pump strokes or dosage of chemicals.

Information must be given on the critical and technical parameters that are to be monitored and recorded in a continuous manner or after defined intervals and on the methods used for measuring and monitoring.

The variability of parameters under typical production conditions must be taken into account.

The HACCP plan must reflect normal and abnormal/emergency operating conditions including a breakdown of the process and it must specify possible corrective actions which are to be applied in the case of abnormal/emergency operating conditions.

5. The applications shall also contain sufficient information on:

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- (a) the risks associated with interdependent processes, and in particular on the outcome of an evaluation of possible indirect impacts, which may:
  - (i) influence the level of risk reduction of a particular process;
  - (ii) arise from transport or storage of any products generated during the process and from the safe disposal of such products, including waste water.
- (b) the risks associated with the intended end use of the products, in particular:
  - (i) the intended end use of any products generated during the process must be specified;
  - (ii) the likely risks for human health and animal health and possible impacts on the environment must be assessed on the basis of the risk reduction estimated in accordance with point 2(d).
- 6. Applications shall be submitted with documentary evidence, in particular:
- (a) a flow diagram showing the functioning of the process;
- (b) the evidence referred to in point 2(d), as well as other evidence aiming to substantiate the information provided in the framework of the application as set out in point 2.
- 7. Applications shall include a contact address for the interested party, which shall include the name and full address, telephone and/or fax number and/or the electronic mail address of a particular person that is responsible as or on behalf of the interested party.]

# ANNEX VIII

# COLLECTION, TRANSPORT AND TRACEABILITY

# CHAPTER I

# **COLLECTION AND TRANSPORT**

#### Section 1

#### Vehicles and containers

- 1. As from the starting point in the manufacturing chain referred to in Article 4(1) of Regulation (EC) No 1069/2009, animal by-products and derived products must be collected and transported in sealed new packaging or covered leak-proof containers or vehicles.
- 2. Vehicles and reusable containers, and all reusable items of equipment or appliances that come into contact with animal by-products or derived products, other than derived products which are placed on the market in accordance with Regulation (EC) No 767/2009 and which are stored and transported in accordance with Annex II to Regulation (EC) No 183/2005, must be maintained in a clean condition.

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In particular, unless they are dedicated to the carriage of particular animal by-products or derived products in a way which avoids cross-contamination, they must be:

- (a) clean and dry before use; and
- (b) cleaned, washed and/or disinfected after each use to the extent necessary to avoid cross-contamination.
- 3. Reusable containers must be dedicated to the carriage of a particular animal by-product or derived product to the extent necessary to avoid cross-contamination.

However, reusable containers may be used, provided the competent authority has authorised such use:

- (a) for the carriage of different animal by-products or derived products provided that they are cleaned and disinfected between the different uses in a manner which prevents cross-contamination;
- (b) for the carriage of animal by-products or derived products referred to in Article 10(f) of Regulation (EC) No 1069/2009, following their use for the carriage of products intended for human consumption, under conditions which prevent cross-contamination.
- 4. Packaging material must be disposed of, by incineration or by other means in accordance with Union legislation.

# Section 2

# **Temperature conditions**

- 1. The transport of animal by-products destined for the production of feed material or raw petfood must take place at an appropriate temperature, in the case of animal by-products from meat and meat products which have been destined for purposes other than human consumption, at a maximum of 7 °C, unless they are used for feeding purposes in accordance with Chapter I of Annex II, in order to avoid any risk to animal or public health.
- 2. Unprocessed Category 3 material destined for the production of feed material or petfood must be stored and transported chilled, frozen or ensiled, unless:
- (a) it is processed within 24 hours after collection or after the end of storage in chilled or frozen form, if the subsequent transport takes place in means of transport in which the storage temperature is maintained;
- (b) in the case of milk, milk-based products or milk-derived products which have not been subject to any of the treatments referred to in Part I of Section 4 of Chapter II of Annex X, it is transported chilled and in insulated containers, unless risks can be mitigated by other measures, due to the characteristics of the material.
- 3. The design of vehicles used for refrigerated transport must ensure the maintenance of an appropriate temperature throughout transport, and allow that temperature to be monitored.

#### Section 3

#### Derogation for collection and transport of Category 3 material comprising of milk, milk-based products and milk-derived products

Section 1 shall not apply to the collection and transportation of Category 3 material comprising of milk, milk-based products and milk derived products by operators of milk-processing establishments which have been approved in accordance with Article 4 of Regulation (EC) No 853/2004, where they are receiving products which they have previously delivered and which are returned to them, in particular from their customers.

#### Section 4

#### **Derogation for collection and transport of manure**

By way of derogation from Section 1, the competent authority may accept the collection and transport of manure transported between two points located on the same farm or between farmers and users in the same Member State under other conditions which provide for the prevention of unacceptable risks to public and animal health.

#### CHAPTER II

#### **IDENTIFICATION**

- 1. All necessary measures must be taken to ensure that:
- (a) consignments of animal by-products and derived products are identifiable and kept separate and identifiable during collection where the animal by-products originate and during transportation;
- (b) a marking substance for the identification of animal by-products or derived products of a specific category is only used for the category for which its use is required under this Regulation, or is established or laid down pursuant to point 4;
- (c) consignments of animal by-products and derived products are dispatched from one Member State to another Member State in packaging, containers or vehicles which are prominently and, at least for the period of transport, indelibly colour-coded for displaying information as provided for in this Regulation on the surface or part of the surface of a packaging, container or vehicle, or on a label or symbol applied to them as follows:
  - (i) in the case of Category 1 materials, using the colour black;
  - (ii) in the case of Category 2 materials (other than manure and digestive tract content), using the colour yellow;
  - (iii) in the case of Category 3 materials, using the colour green with a high content of blue to ensure that it is clearly distinguishable from the other colours;
  - (iv) in the case of imported consignments, the colour referred to for the respective material under points (i), (ii) and (iii), as from the time when the consignment has passed the border inspection post of first entry into the Union.

- 2. During transport and storage, a label attached to the packaging, container or vehicle must:
- (a) clearly indicate the category of the animal by-products or of the derived products; and
- (b) bear the following words visibly and legibly displayed on the packaging, a container or vehicle, as applicable:
  - (i) in the case of Category 3 material, 'not for human consumption';
  - (ii) in the case of Category 2 material (other than manure and digestive tract content) and derived products from Category 2 material, 'not for animal consumption'; however, when Category 2 material is intended for the feeding of animals referred to in Article 18(1) of Regulation (EC) No 1069/2009 under the conditions provided for or laid down in accordance with that Article, the label shall instead indicate 'for feeding to ...' completed with the name of the specific species of those animals for the feeding of which the material is intended;
  - (iii) in the case of Category 1 material and derived products from Category 1 material where they are destined for
    - disposal, 'for disposal only';
    - the manufacture of petfood, 'for manufacture of pet food only';
    - the manufacture of a derived product referred to in Article 36 of Regulation (EC) No 1069/2009, 'for manufacture of derived products only. Not for human or animal consumption or for application to land';
  - (iv) in the case of milk, milk-based products, milk-derived products, colostrum and colostrum products, 'not for human consumption';
  - (v) in the case of gelatine produced from Category 3 material, 'gelatine suitable for animal consumption';
  - (vi) in the case of collagen produced from Category 3 material, 'collagen suitable for animal consumption';
  - (vii) in the case of raw petfood, 'as pet food only';
  - (viii) in the case of fish and derived products from fish intended for feed for fish, and treated and packaged before distribution, the name and address of the feed manufacturing establishment of origin, marked clearly and legibly, and
    - in the case of fishmeal from wild fish, bearing the words 'contains fishmeal from wild fish only may be used for the feeding of farmed fish of all species';
    - in the case of fishmeal from farmed fish, bearing the words 'contains fishmeal from farmed fish of the [...] species only – may only be used for the feeding of farmed fish of other fish species';
    - in the case of fishmeal from wild fish and from farmed fish, bearing the words 'contains fishmeal from wild fish and farmed fish of the [...] species may only be used for the feeding of farmed fish of other fish species';

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- (ix) in the case of blood products from equidae for purposes other than in feed, 'blood and blood products from equidae. Not for human or animal consumption';
- (x) in the case of horns, hooves and other materials for the production of organic fertilisers and soil improvers referred to in Section 12 of Chapter II of Annex XIV, 'not for human or animal consumption';
- (xi) in the case of organic fertilisers and soil improvers, 'organic fertilisers or soil improvers/no grazing of farmed animals or use of crops as herbage during at least 21 days following application';
- (xii) in the case of material used for feeding in accordance with Section 1 of Chapter II of Annex VI, the name and the address of the collection centre, and the indication 'not for human consumption';
- (xiii) in the case of manure and digestive tract content, 'manure';
- (xiv) in the case of intermediate products, on the outer packaging, bearing the words 'for medicinal products/veterinary medicinal products/medical devices/active implantable medical devices/in vitro diagnostic medical devices/laboratory reagents only';
- (xv) in the case of research and diagnostic samples, the words 'for research and diagnostic purposes', instead of the label text laid down in point (a);
- (xvi) in the case of trade samples, the words 'trade sample not for human consumption', instead of the label text laid down in point (a);
- (xvii) [<sup>F5</sup>in the case of display items, the words 'display item not for human consumption', instead of the label text laid down in point (a);
- (xviii) in the case of fish oil for the production of medicinal products referred to in Chapter XIII of Annex XIII, the words 'fish oil for the production of medicinal products', instead of the label text laid down in point (a);]
- (xix) [<sup>F1</sup>in the case of manure which has been subject to the lime treatment set out in point I of Section 2 of Chapter IV of Annex IV, the words 'manurelime-mixture';
- (xx) in the case of processed manure which has been subject to the treatment set out in point (b) and (c) of Section 2 of Chapter I of Annex XI, the words 'processed manure'.]
- (c) However, the label referred to in point (b)(xi) shall not be required for the following organic fertilisers and soil improvers:
  - (i) in ready-to-sell packages of not more than 50 kg in weight for use by the final consumer; or
  - (ii) in big bags of not more than 1 000 kg in weight, provided that:
    - they are authorised by the competent authority of the Member State where the organic fertiliser or soil improver is to be applied to land,
    - it is indicated on those bags that they are not destined for application to land to which farmed animals have access.

- 3. Member States may establish systems or lay down rules for the colour-coding of packaging, containers or vehicles used for the transport of animal by-products and derived products originating in and remaining on their territory, provided that those systems or rules do not confuse the colour-coding system provided for in point 1(c).
- 4. Member States may establish systems or lay down rules for the marking of animal byproducts originating in and remaining on their territory provided that those systems or rules do not conflict with the marking requirements set out for derived products in Chapter V of this Annex.
- 5. By way of derogation from points 3 and 4, Member States may use the systems or rules referred to in those points for animal by-products originating in but not intended to remain on their territory if the Member State or third country of destination has communicated its agreement.
- 6. However:
- (a) points 1 and 2 of this Chapter shall not apply to the identification of Category 3 material comprising of milk, milk-based products and milk-derived products, by operators of milk-processing establishments which have been approved in accordance with Article 4 of Regulation (EC) No 853/2004, where they are receiving products which they have previously delivered and which are returned to them, in particular from their customers;
- (b) the competent authority may accept the identification of manure which is transported between two points located on the same farm or between farms and users located in the same Member State by other means, by way of derogation from points 1 and 2;
- (c) compound feeds as defined in Article 3(2)(h) of Regulation (EC) No 767/2009 which have been manufactured from animal by-products or from derived products and which are packaged and placed on the market as feed in accordance with Article 4 of Regulation (EC) No 767/2009 do not have to be identified in accordance with point 1 and they do not have to be labelled in accordance with point 2.

# CHAPTER III

# COMMERCIAL DOCUMENTS AND HEALTH CERTIFICATES

1. During transportation, a commercial document in accordance with the model set out in this Chapter, or, when required by this Regulation, a health certificate must accompany animal by-products and derived products.

However, such document or certificate shall not be necessary, provided that:

- (a) derived products from Category 3 material and organic fertilisers and soil improvers are supplied within the same Member State by retailers to final users other than business operators;
- (b) milk, milk-based products and milk-derived products which are Category 3 materials are collected and returned to operators of milk-processing establishments, which have been approved in accordance with Article 4 of Regulation (EC) No 853/2004, if those operators are receiving products, in particular from their customers, which they have previously delivered;

- (c) compound feeds as defined in Article 3(2)(h) of Regulation (EC) No 767/2009 which have been manufactured from animal by-products or from derived products, are placed on the market packaged and labelled in accordance with Article 4 of Regulation (EC) No 767/2009.
- 2. The commercial document must be produced at least in triplicate (one original and two copies). The original must accompany the consignment to its final destination. The receiver must retain it. The producer must retain one of the copies and the carrier the other.

Member States may require that proof of the arrival of the consignments is provided by the TRACES system or by a fourth copy of the commercial document which is sent back by the receiver to the producer.

- 3. Health certificates must be issued and signed by the competent authority.
- 4. A commercial document in accordance with the model set out under point 6 shall accompany animal by-products and derived products as from the starting point in the manufacturing chain referred to in Article 4(1) of Regulation (EC) No 1069/2009, during transportation within the Union.

However, in addition to the authorisation to transmit information by way of an alternative system as referred to in the second subparagraph of Article 21(3) of Regulation (EC) No 1069/2009, the competent authority may authorise that animal by-products and derived products which are transported on its territory are accompanied by:

- (a) a different commercial document, in paper or in electronic form, provided that such commercial document contains the information referred to in point (f) of the Notes under point 6 of this Chapter;
- (b) a commercial document in which the quantity of the material is expressed in weight or volume of the material or in the number of packages.
- 5. Records and related commercial documents or health certificates shall be kept for a period of at least two years for presentation to the competent authority.
- 6. Model commercial document

Notes

(a) Commercial documents shall be produced, according to the layout of the model appearing in this Chapter.

It shall contain, in the numbered order that appears in the model, the attestations that are required for the transportation of animal by-products and derived products.

(b) It shall be drawn up in one of the official languages of the Member State of origin and of the Member State of destination, as appropriate.

However, it may also be drawn up in other official Union languages, if accompanied by an official translation or if previously agreed by the competent authority of the Member State of destination.

- (c) The original of each commercial document shall consist of a single sheet of paper, both sides, or, where more text is required it shall be in such a form that all sheets of paper needed are demonstrably part of an integrated whole and indivisible.
- (d) If for reasons of identification of the items of the consignment, additional sheets of paper are attached to the commercial document, these sheets of paper shall also be

considered as forming part of the original document by the application of the signature of the person responsible for the consignment, on each of the pages.

- (e) When the commercial document, including additional sheets of paper referred to in point (d), comprises more than one page, each page shall be numbered (page number) of (total number of pages) at the bottom of the page and shall bear the code number of the document that has been designated by the responsible person at the top of the page.
- (f) The original of the commercial document must be completed and signed by the responsible person.

The commercial document must specify:

- (i) the date on which the material was taken from the premises;
- (ii) the description of the material, including
  - the identification of the material according to one of the categories referred to in Articles 8, 9 and 10 of Regulation (EC) No 1069/2009,
  - the animal species and the specific reference to the applicable point in Article 10 of Regulation (EC) No 1069/2009 for Category 3 material and products derived therefrom which are destined for feeding and,
  - if applicable, the ear-tag number of the animal;
- (iii) the quantity of the material, in volume, weight or number of packages;
- (iv) the place of origin of the material, from where the material is dispatched;
- (v) the name and the address of the carrier of the material;
- (vi) the name and the address of the receiver and, if applicable, its approval or registration number, which has been issued under Regulation (EC) No 1069/2009 or Regulations (EC) No 852/2004, (EC) No 853/2004 or (EC) No 183/2005, as applicable;
- (vii) if appropriate, the approval or registration number of the establishment or plant of origin, which has been issued under Regulation (EC) No 1069/2009 or Regulations (EC) No 852/2004, (EC) No 853/2004 or (EC) No 183/2005, as applicable, and the nature and the methods of the treatment.
- (g) The colour of the signature of the responsible person shall be different to that of the printing.
- (h) The document reference number and the local reference number shall only be issued once for the same consignment.

# [<sup>F10</sup>Commercial document

For the transport of animal by-products and derived products not intended for human consumption in accordance with Regulation (EC) No 1069/2009 within the European Union]

EUF	UROPEAN UNION Commercial docu			
	l.1.	Consignor Name Address	I.2. Document reference No         I.2.a. Local reference No           I.3. Central competent authority	
ent		Postcode	I.4. Local competent authority	
l E	1.5.	Consignee	1.6.	
nsić		Name Address		
8			1.7.	
tche		Postcode Tel.		
of dispatched consignment	1.8.	Country of origin ISO code I.9. Region of origin Code	I.10. Country of ISO code I.11. Region of Code destination	
ails	112	Place of origin	I.13. Place of destiantion	
Bet	1.12.		Establishment  Other	
Part I: Details				
Pa		Name Approval number Address	Name Approval number Address	
		Postcode	Postcode	
	1.14.	Place of loading	I.15. Date of departure	
	I.16.	Means of transport	I.17. Transporter	
		Aeroplane	Name Approval number Address	
		Identification	Postcode Member State	
	1 1 0	Description of commodity	I.19. Commodity code (CN code)	
	1.10.	Description of commonly		
			I.20. Quantity	
	1.21.	Temperature of product	I.22. Number of packages	
		Ambient Chilled Frozen	Controlled temperature	
	1.23.	Seal/Container No	I.24. Type of packaging	
	1.25.	Commodities certified for:	· · · · · · · · · · · · · · · · · · ·	
		Animal feedingstuff		
	1.26.		I.27. Transit through Member States Member State ISO Code	
			Member State ISO Code Member State ISO Code	
	1.28.	Export	1.29.	
		Third country ISO Code Exit point Code		
	1.30.			
	1.31.	Identification of the commodities		
		Species Nature of Category Treatme (scientific name) commodity	Approval number of establishments ent type Manufacturing plant Batch number	

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			Animal by-products/derived products not intended for human consumption			
	II. Health informat	lion	II.a. Certificate reference number	II.b.		
	II.1. Declaration by	the consignor				
	I, the undersign	ned, declare that:				
	II.1.1. the information	n in Part I is factually correct;				
		s have been taken to avoid contamination of the animal by-products or derived products with pathogenic agents and cross-				
		contamination between various categories.				
	Notes:					
2	Part I:					
	- Box reference I.9 and I.11: if appropriate.					
	<ul> <li>Box reference I.12, I.13 and I.17: approval number or registration number. In the case of processed manure indicate in Box I.13 the approval or registration number of plant or holding of destination.</li> </ul>					
	<ul> <li>Box reference I.14: complete if different from 'I.1. Consignor'.</li> </ul>					
	- Box reference I.25: technical use: any use other than for animal consumption.					
- Box reference I.31:						
	Animal species:	For Category 3 material and products derived the Ruminants, Non-Ruminants, Mammalia, Pesca		rial. Select from the following: Aves,		
	Nature of commodity:	Enter a commodity chosen from the following lik residues', 'digestive tract content', 'dog-chews 'hydrolysed proteins', 'organic fertilisers', 'pet 'rendered fats', 'compost', 'processed manur processing', 'dicalciumphosphate', 'tricalciumpi 'wool', 'hair', 'pig bristles', 'feathers', 'animal by	s', 'fishmeal', 'flavouring innards', 'gela food', 'processed animal protein', 'pr e', 'fish oil', 'milk products', 'centrifu hosphate', 'collagen', 'egg products', 's	atine', 'greaves', 'hides and skins', ocessed pet food', 'raw pet food', ge or separator sludge from milk serum of equidae', 'game trophies',		
	Category: Specify Category 1, 2 or 3 materials.					
		In case of Category 3 material, indicate the point by-product concerned (e.g. Article 10(a), Article		1069/2009 that refers to the animal		
		In the case of Category 3 material for use in ra by-products are referred to in Article 10(a) or	in Article 10(b)(i) or (ii) of Regulation (	EC) No 1069/2009.		
		In the case of hides and skins and products de by-products or derived products are referred to	o in Article 10(b)(iii) or in Article 10(n)	of Regulation (EC) No 1069/2009.		
		Where the consignment is made of more the containers per category of materials.	an one category, indicate the quantity	y and if applicable the number of		
	Treatment type:	For treated hides and skins indicate the treatm	nent:			
		<ul><li>'(a)' for dried;</li><li>'(b)' for dry-salted or wet-salted for at least 14</li></ul>	dave prior to dispatch:			
		(c) for salted for seven days in sea salt with				
		For Categories 1 and 2 materials describe the method (choose a method from 1 to 5 referred	method of processing or transformation	on. Indicate the relevant processing		
		For Category 3 materials and derived products the nature and the methods of the treatment. referred to in Chapter III of Annex IV to Regul	Indicate the relevant processing meth			
	Batch number:	Enter batch number or ear tag number, if appl	licable.			
	Part II:					
	— The signature must l	be in a different colour to that of the printing.				
	Signature					
	Done at on					
		(place)		(date)		
	(signature of the responsible person/consignor) (name, in capital letters)					

#### CHAPTER IV

#### RECORDS

#### Section 1

#### **General provisions**

- 1. The records as referred to in Article 22(1) of Regulation (EC) No 1069/2009 for animal by-products and derived products, other than compound feeds as defined in Article 3(2)(h) of Regulation (EC) No 767/2009, which have been manufactured from animal by-products or from derived products and which are placed on the market in accordance with Article 4 of Regulation (EC) No 767/2009, shall contain:
- (a) a description of:
  - (i) the animal species for Category 3 material and derived products therefrom, destined for use as feed material and, if applicable, in the case of whole carcases and heads, the ear-tag number;
  - (ii) the quantity of the material;
- (b) in the case of records kept by any person consigning animal by-products or derived products, the following information:
  - (i) the date on which the material was taken from the premises;
  - (ii) the name and the address of the transporter and of the receiver and, if applicable, their approval or registration number;
- (c) in the case of records kept by any person transporting animal by-products or derived products, the following information:
  - (i) the date on which the material was taken from the premises;
  - (ii) the place of origin of the material, from where the material is dispatched;
  - (iii) the name and the address of the receiver and, if applicable, its approval or registration number;
- (d) in the case of records kept by any person receiving animal by-products or derived products, the following information:
  - (i) the date of reception of the material;
  - (ii) the place of origin of the material, from where the material is dispatched;
  - (iii) the name and address of the transporter.
- 2. By way of derogation from point 1 of this Section, operators do not have to keep the information referred to in point 1(a) and points (b)(i), (c)(i) and (iii) and d(ii) and (iii) separately, if they keep a copy of the commercial document laid down in Chapter III for each consignment and make such information available in conjunction with the other information required under point 1 of this Section.

3. Operators of incineration plants and co-incineration plants shall keep records of the quantities and category of the animal by-products and derived products incinerated or co-incinerated, as applicable, and the date at which those operations were carried out.

# Section 2

# Additional requirements in case of use for special feeding purposes

In addition to the records required in accordance with Section 1, operators shall keep the following records in relation to relevant material if animal by-products are used for special feeding purposes in accordance with Chapter II of Annex VI:

- 1. in the case of final users, the quantity used, the animals that it is intended to be fed to and the date of use;
- 2. in the case of collection centres:
  - (i) the quantity handled or treated in accordance with point 4 of Section 1 of Chapter I of Annex VI;
  - (ii) the name and address of each final user using the material;
  - (iii) the premises to which the material is taken for use;
  - (iv) the quantity dispatched; and
  - (v) the date on which the material was dispatched.

# Section 3

# **Requirements in case of certain fur animals**

The operator of the farm referred to in Chapter I of Annex II shall keep records at least of:

- (a) the number of furs and carcases of animals fed with materials originating of their own species; and
- (b) each consignment in order to ensure the traceability of the material.

# Section 4

# Requirements for the application of certain organic fertilisers and soil improvers to land

The person responsible for land to which organic fertilisers and soil improvers, other than the materials referred to in the second paragraph of Chapter II of Annex II are applied and to which farmed animals have access or from which herbage is cut for feeding to farmed animals, shall keep records of the following for a period of at least two years:

- 1. the quantities of organic fertilisers and soil improvers applied;
- 2. the date on which the organic fertilisers and soil improvers were applied to land and the places of such application;

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Commission Regulation (EU) No 142/2011. (See end of Document for details)	

3. the dates, following the application of the organic fertiliser or soil improver, on which livestock has been allowed to graze on the land or on which the land has been cut for herbage to be used for feeding.

#### Section 5

# Requirements for animal by-products derived from aquatic animals and feeding of fish

Processing plants producing fishmeal or other feed originating from aquatic animals shall keep records of the following:

- (a) the quantities produced each day;
- (b) the species of origin, including an indication of whether the aquatic animals were caught in the wild or produced in aquaculture;
- (c) in the case of fishmeal from farmed fish which is intended for feeding to farmed fish of another species, the scientific name of the species of origin.

#### Section 6

#### **Requirements for the burning and burial of animal by-products**

In the case of burning or burial of animal by-products as provided for in Article 19(1) of Regulation (EC) No 1069/2009, the person responsible for such burning or burial shall keep records of the following:

- (a) the quantities, categories and species of animal by-products burned or buried;
- (b) the date and place of burning and burial.

# Section 7

#### **Requirements for photogelatine**

Operators of approved photographic factories referred to in Section 11 of Chapter II of Annex XIV shall keep records detailing the purchases and uses of photogelatine, as well as the disposal of residues and surplus material.

# CHAPTER V

# MARKING OF CERTAIN DERIVED PRODUCTS

- 1. In processing plants for the processing of Category 1 or Category 2 material, derived products shall be permanently marked with glyceroltriheptanoate (GTH) in such a way that:
- (a) GTH is added to derived products that have undergone a preceding sanitising thermal treatment at a core temperature of at least 80 °C and remain subsequently protected from re-contamination;

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- (b) all derived products contain homogenously throughout the substance a minimum concentration of at least 250 mg GTH per kg fat.
- 2. The operators of processing plants referred to in point 1 shall have in place a system of monitoring and recording of parameters suitable to demonstrate to the competent authority that the required homogeneous minimum concentration of GTH is achieved.

That monitoring and recording system shall include the determination of the content of intact GTH as triglyceride in a cleaned petroleum-ether 40-70 extract of GTH from samples taken at regular intervals.

- 3. The marking with GTH shall not be required for:
- (a) liquid derived products destined for biogas or composting plants;
- (b) derived products used for feeding to fur animals in accordance with Chapter I of Annex II;
- (c) biodiesel produced in accordance with point D of Section 2 of Chapter IV of Annex IV;
- (d) derived products obtained in accordance with Article 12(a)(ii) and (b)(ii) and Article 13(a)(ii) and (b)(ii) and Article 16(e) of Regulation (EC) No 1069/2009, where such products are:
  - (i) moved by a closed conveyer system, which may not be by-passed, and provided such a system has been authorised by the competent authority, from the processing plant for:
    - immediate direct incineration or co-incineration,
    - immediate use in accordance with a method approved for animal by-products of Category 1 and Category 2 in accordance with Chapter IV of Annex IV; or
  - (ii) [<sup>F5</sup>intended for research and other specific purposes as referred to in Article 17 of Regulation (EC) No 1069/2009 which have been authorised by the competent authority;]
- (e) [<sup>F5</sup>renewable fuels produced from rendered fats, which are derived from Category 2 materials, in accordance with point J of Section 2 of Chapter IV of Annex IV.]

# [<sup>F11</sup>CHAPTER VI

# TRANSPORT OF DEAD PET ANIMALS

The conditions in points 1 to 3 of Article 48 of Regulation (EC) No 1069/2009 regarding the advance authorisation by the competent authority in the Member States of destination and the use of TRACES shall not be required in the case of the transport of a dead pet animal for incineration in an establishment or plant located in the border region of another Member State sharing a common border when the Member States conclude a bilateral agreement on the condition of the transport.]

#### **Textual Amendments**

**F11** Inserted by Commission Regulation (EU) No 294/2013 of 14 March 2013 amending and correcting Regulation (EU) No 142/2011 implementing Regulation (EC) No 1069/2009 of the European Parliament

and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (Text with EEA relevance).

#### ANNEX IX

# **REQUIREMENTS APPLICABLE TO CERTAIN APPROVED AND REGISTERED ESTABLISHMENTS AND PLANTS**

#### CHAPTER I

#### MANUFACTURING OF PETFOOD

Establishments or plants manufacturing petfood as referred to in Article 24(1)(e) of Regulation (EC) No 1069/2009 shall have adequate facilities for:

- (a) storing and treating incoming material in complete safety; and
- (b) disposing of unused animal by-products remaining after the production of the products in accordance with this Regulation, or such material must be sent to an incineration plant, a co-incineration plant, a processing plant or, in the case of Category 3 material, to a biogas or composting plant in accordance with Articles 12, 13 and 14 of Regulation (EC) No 1069/2009 and with this Regulation.

#### CHAPTER II

### HANDLING OF ANIMAL BY-PRODUCTS AFTER THEIR COLLECTION

The requirements of this Chapter shall apply to the storage of animal by-products, as referred to in Article 24(1)(i) of Regulation (EC) No 1069/2009 and to the following operations involving the handling of animal by-products after their collection, as referred to in Article 24(1)(h) of that Regulation:

- (a) sorting;
- (b) cutting;
- (c) chilling;
- (d) freezing;
- (e) salting or other preservation processes;
- (f) removal of hides and skins;
- (g) removal of specified risk material;
- (h) operations involving the handling of animal by-products which are carried out in compliance with obligations under Union veterinary legislation, such as post-mortem examination or the taking of samples;

- (i) hygienisation/pasteurisation of animal by-products destined for transformation into biogas or composting, prior to such transformation or composting in another establishment or plant in accordance with Annex V hereto;
- (j) sieving.

#### Section 1

### **General requirements**

- 1. Premises and facilities where intermediate operations are carried out shall meet at least the following requirements:
- (a) They must be adequately separated from thoroughfares through which contamination may be spread and from other premises such as slaughterhouses. The layout of plants shall ensure the total separation of Category 1 and Category 2 material from Category 3 material respectively, from reception until dispatch, unless in a completely separate building.
- (b) The plant must have a covered space to receive and dispatch animal by-products, unless the animal by-products are being discharged through installations which prevent the spreading of risks to public and animal health, such as through closed tubes for liquid animal by-products.
- (c) The plant must be constructed in such a way that it is easy to clean and disinfect. Floors must be laid down in such a way as to facilitate the draining of liquids.
- (d) The plant must have adequate facilities including lavatories, changing rooms, washbasins for staff and, if appropriate, office space which can be made available to the staff performing official controls.
- (e) The plant must have appropriate arrangements for protection against pests, such as insects, rodents and birds.
- (f) Where it is necessary for the purpose of achieving the objectives of this Regulation, plants must have suitable temperature-controlled storage facilities of sufficient capacity for maintaining animal by-products at appropriate temperatures and designed to allow the monitoring and recording of those temperatures.
- 2. The plant shall be equipped with adequate facilities for cleaning and disinfecting the containers or receptacles in which animal by-products are received and for the vehicles, other than ships, in which they are transported. Adequate facilities shall be available for the disinfecting of vehicle wheels.

# Section 2

#### Hygiene requirements

- 1. The sorting of animal by-products shall be carried out in such a way as to avoid any risk of the propagation of animal diseases.
- 2. At all times during storage, animal by-products shall be handled and stored separately from other goods and in such a way as to prevent any propagation of pathogens.

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3. Animal by-products shall be stored properly, including under appropriate temperature conditions, until re-dispatched.

#### Section 3

#### Processing standards for hygienisation/pasteurisation

Hygienisation/pasteurisation as referred to in point (i) of the initial paragraph of this Chapter shall be carried out in accordance with the processing standards referred to in point 1 of Section 1 of Chapter I of Annex V or in accordance with alternative transformation parameters which have been authorised in accordance with point 1 of Section 2 of Chapter III of the same Annex.

## CHAPTER III

# **REQUIREMENTS FOR STORAGE OF DERIVED PRODUCTS**

#### Section 1

#### **General requirements**

Premises and facilities storing derived products shall meet at least the following requirements:

- 1. Premises and facilities storing derived products from Category 3 material must not be at the same site as premises storing derived products from Category 1 or Category 2 material, unless cross-contamination is prevented due to the layout and management of the premises, such as by means of storage in completely separate buildings.
- 2. The plant must:
  - (a) have a covered space to receive and dispatch the derived products, unless the derived products are:
    - (i) being discharged through installations which prevent the spreading of risks to public and animal health, such as through closed tubes for liquid products; or
    - (ii) received in packaging, such as in big bags, or in covered leak-proof containers or means of transport;
  - (b) be constructed in such a way that it is easy to clean and disinfect. Floors must be laid down in such a way as to facilitate the draining of liquids;
  - (c) have adequate facilities including lavatories, changing rooms and washbasins for staff;
  - (d) have appropriate arrangements for protection against pests, such as insects, rodents and birds.
- 3. The plant must have adequate facilities for cleaning and disinfecting the containers or receptacles in which the derived products are received and the vehicles, other than ships, in which they are transported.
- 4. Derived products must be stored properly until redispatched.

#### Section 2

#### Specific requirements for storage of certain milk, milk-based products and milk-derived products

- 1. The storage of the products referred to in Part II of Section 4 of Chapter II of Annex X shall take place at an appropriate temperature to avoid any risk to public or animal health in a dedicated approved or registered storage establishment or plant or in a dedicated, separate storage area within an approved or registered storage establishment or plant.
- 2. Samples of the final products taken during storage or at the time of withdrawal from storage, shall at least comply with the microbiological standards set out in Chapter I of Annex X.

#### CHAPTER IV

#### **REGISTERED OPERATORS**

- 1. Operators of registered plants or establishments or other registered operators shall handle animal by-products and derived products under the following conditions:
- (a) premises must be constructed in a way permitting their effective cleaning and disinfection, where appropriate;
- (b) premises must have appropriate arrangements for protection against pests, such as insects, rodents and birds;
- (c) installations and equipment must be kept in hygienic condition, where necessary;
- (d) animal by-products and derived products must be stored under conditions preventing contamination.
- 2. Operators shall keep records in a form which is accessible to the competent authority.
- 3. Registered operators transporting animal by-products or derived products, other than between premises of the same operator, shall in particular:
- (a) have information at their disposal with regard to the identification of their vehicles, which allows the verification of the use of the vehicles for the transport of animal by-products or derived products;
- (b) clean and disinfect their vehicles, as appropriate;
- (c) take all other necessary measures to prevent contamination and the spreading of diseases communicable to humans or animals.

# [<sup>F4</sup>CHAPTER V

# **CONTAINMENT METHODS**

#### Section 1

#### **General provisions**

- 1. Materials resulting from a containment method may be used or disposed of only within the Member State where that containment method is authorised by the competent authority.
- 2. The competent authority of a Member State shall make the results of official controls available to the competent authority of another Member State upon request, where a containment method is used for the first time in that Member State, in order to facilitate the introduction of the new containment method.

## Section 2

## Methodology

- A. Aerobic maturation and storage of dead-on-farm pigs and certain other porcine material with subsequent incineration or co-incineration.
- 1. Member States concerned

The process of aerobic maturation and storage of dead-on-farm pigs and certain other porcine material with subsequent incineration or co-incineration may be used in France, Ireland, Latvia, Portugal and the United Kingdom.

Following aerobic maturation and storage of material, the competent authority of the Member State concerned must ensure that the materials are collected and disposed of within the territory of that Member State.

2. Starting materials

For this process, only the following materials of animals of the porcine species may be used:

- (a) Category 2 materials referred to in Article 9(f)(i) to (iii) of Regulation (EC) No 1069/2009;
- (b) Category 3 materials referred to in Article 10(h) of Regulation (EC) No 1069/2009.

This method is only applicable to the disposal of animals of the porcine species originating in the same holding, provided this holding is not subject to restrictions due to a suspected or confirmed outbreak of a serious transmissible disease affecting animals of the porcine species. This method may not be used for animals which have died due to those diseases or have been killed for diseases control purposes, or parts of those animals.

- 3. Methodology
- 3.1. General principles

The method is a process authorised by the competent authority.

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The site must be constructed and laid out in accordance with Union legislation for the protection of the environment, in order to prevent odours and risks to soil and groundwater.

The operator must:

- (a) take preventive measures against access of animals and put in place a documented pest control programme;
- (b) put in place procedures to prevent the spreading of diseases;
- (c) put in place procedures to prevent the spreading of used sawdust outside the closed system.

The process must be carried out in a closed system which consist of several cells, with a waterproof floor and delimited by solid walls. Any waste water must be collected; the cells must be connected with a drainpipe fitted with a 6 mm grid to capture solids.

Size and number of the cells must be adapted to the mortality level defined in the permanent written procedure referred to in Article 29(1) to (3) of Regulation (EC) No 1069/2009 with sufficient capacity for farm mortalities occurring during an eight-month period at least.

- 3.2. Phases
- 3.2.1. Filling and storage phase

The fallen pigs and other porcine material must be individually covered in sawdust and piled up until the cell is full. First a layer of at least 30 centimetres of sawdust must be placed on the ground. The carcasses and other porcine material must then be placed on this first layer of sawdust and each layer of carcasses and other porcine material must be covered with a layer of sawdust at least 30 cm thick.

Personnel must not walk on the stored material.

3.2.2. Maturing phase

When the cell is full and a rise in temperature allows the degradation of all the soft tissues, the maturation period starts and must last at least 3 months.

At the end of the filling and storage phase and during all of the maturation phase, the operator must monitor the temperature in each cell with a temperature sensor placed between 40 cm and 60 cm beneath the pile surface of the latest built layer.

The electronic reading and monitoring of the temperature must be recorded by the operator.

At the end of the filling and storage phase, the temperature monitoring is an indicator of a satisfactory pile layout. The temperature must be measured by an automatic recording device. The aim is to reach 55 °C during 3 consecutive days, revealing that the maturing process is active and that the pile layout is effective and that the maturing phase has started.

The operator must monitor the temperature once a day and the following measures shall be taken depending on the outcome of these measurements:

- (a) where the temperature of 55 °C or more is maintained during 3 consecutive days, the pile may be removed after a 3 consecutive months maturing phase, or may remain stored on the premises awaiting a later removal;
- (b) where the temperature of 55 °C is not reached during 3 consecutive days, measures defined in the permanent written procedure referred to in Article 29(1) to (3) of Regulation (EC) No 1069/2009 must be set by the operator; if needed, the competent

authority may stop the processing method and the material must be disposed of in compliance with Article 13 of the aforementioned Regulation.

A time limit for the storage phase may be determined by the competent authority.

3.2.3. Transport and incineration or co-incineration

The transport of the resulted material after the maturation phase to the approved incineration or co-incineration plant is subject to controls referred to in Regulation (EC) No 1069/2009 or Directive 2008/98/EC.

- B. Hydrolysis with subsequent disposal
- 1. Member States concerned

The process of hydrolysis with subsequent disposal may be used in Ireland, Spain, Latvia, Portugal and the United Kingdom.

Following hydrolysis, the authorising competent authority must ensure that the materials are collected and disposed of within the same Member State referred to above.

2. Starting materials

For this process, only the following materials of porcine origin may be used:

- (a) Category 2 materials referred to in Article 9(f)(i) to (iii) of Regulation (EC) No 1069/2009;
- (b) Category 3 materials referred to in Article 10(h) of that Regulation.

This method is only applicable to the disposal of animals of the porcine species originating in the same holding and provided this holding is not subject to prohibition due to a suspected or confirmed outbreak of a serious transmissible disease affecting animals of the porcine species, or animals that have been killed for disease control purposes.

3. Methodology

Hydrolysis with subsequent disposal is a temporary storage on the spot. It shall be carried out according to the following standards:

- (a) Following their collection on a holding for which the competent authority has authorised the use of the processing method, based on an assessment of the animal density of the holding, the likely mortality rate and the potential risks for public and animal health which may arise, the animal by-products must be placed into a container which has been constructed in accordance with point (b) ('the container') and which has been placed at a dedicated site in accordance with points (c) and (d) ('the dedicated site').
- (b) The container must:
  - (i) have a device to close it;
  - (ii) be waterproof, leak-proof and hermetically sealed;
  - (iii) be coated in a way which prevents corrosion;
  - (iv) be equipped with a device for controlling emissions in accordance with point (e).

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(c) The container must be placed in a dedicated site which is physically separate from the holding.

That site must have dedicated access routes for the movement of materials and for collection vehicles.

- (d) The container and the site must be constructed and laid out in accordance with Union legislation for the protection of the environment, in order to prevent odours and risks to soil and groundwater.
- (e) The container must be linked to a pipe for gaseous emissions, which must be equipped with appropriate filters to prevent the transmission of diseases communicable to humans and animals.
- (f) The container must be closed for the process of hydrolysis for a period of at least three months, in such a way that any unauthorised opening is prevented.
- (g) The operator must put in place procedures to prevent the transmission of diseases communicable to humans or animals by movements of personnel.
- (h) The operator must:
  - (i) take preventive measures against birds, rodents, insects and other vermin;
  - (ii) put in place a documented pest control programme.
- (i) The operator must keep records of:
  - (i) any placing of material into the container;
  - (ii) any collection of hydrolysed material from the container.
- (j) The operator must empty the container at regular intervals for a check:
  - (i) for the absence of corrosion;
  - (ii) to detect and prevent possible leakage of liquid materials into the ground.
- (k) Following hydrolysis, the materials must be collected, used and disposed of in accordance with Article 13(a), (b), (c) or Article 13(e)(i) of Regulation (EC) No 1069/2009 or Article 14 of that Regulation for Category 3 materials.
- (1) The process must be carried out in a batch mode.
- (m) Any other handling or use of the hydrolysed materials, including their application to land, shall be prohibited.]

#### ANNEX X

## FEED MATERIALS

#### CHAPTER I

#### GENERAL REQUIREMENTS FOR THE PROCESSING AND PLACING ON THE MARKET

Microbiological standards for derived products

The following microbiological standards shall apply to derived products:

Samples of the final products taken during or on withdrawal from storage at the processing plant must comply with the following standards:

Salmonella: absence in 25 g: n = 5, c = 0, m = 0, M = 0Enterobacteriaceae: n = 5, c = 2, m = 10, M = 300 in 1 g

where:

n	= number of samples to be tested;
m	= threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria in all samples does not exceed m;
М	= maximum value for the number of bacteria; the result is considered unsatisfactory if the number of bacteria in one or more samples is M or more; and
с	<ul> <li>number of samples the bacterial count of which may be between m and M, the sample still being considered acceptable if the bacterial count of the other samples is m or less.</li> </ul>

However, the microbiological standards set out in this Chapter shall not apply to rendered fats and fish oil from the processing of animal by-products, when the processed animal protein, which is obtained during the same processing, is subject to sampling to ensure compliance with those standards.

#### CHAPTER II

#### SPECIFIC REQUIREMENTS FOR PROCESSED ANIMAL PROTEIN AND OTHER DERIVED PRODUCTS

#### Section 1

#### Specific requirements for processed animal protein

A. Raw materials

Only animal by-products which are Category 3 material or products which are derived from such animal by-products, other than the Category 3 materials referred to in Article 10(n), (o) and (p) of Regulation (EC) No 1069/2009, may be used for the production of processed animal protein.

B. Processing standards

1. Processed animal protein of mammalian origin must have been submitted to processing method 1 (pressure sterilisation) as set out in Chapter III of Annex IV.

However,

- (a) porcine blood or fractions of porcine blood for the production of bloodmeal may have been submitted instead to any of the processing methods 1 to 5 or processing method 7 as set out in Chapter III of Annex IV, provided that in the case of processing method 7, a heat treatment throughout its substance at a temperature of 80 °C has been applied;
- (b) processed animal protein of mammalian origin
  - (i) may have been submitted to any of the processing methods 1 to 5 or processing method 7, as set out in Chapter III of Annex IV, provided that it is subsequently disposed of or used as a fuel for combustion;
  - (ii) where it is exclusively destined for use in petfood, it may have been submitted to any of the processing methods 1 to 5 or processing method 7, as set out in Chapter III of Annex IV, provided that it is:
    - transported in dedicated containers that are not used for the transport of animal by-products or feedingstuffs for farmed animals, and
    - consigned directly from a processing plant for Category 3 material to the petfood plant or to an approved storage plant, from where it is directly consigned to a petfood plant.
- 2. Non-mammalian processed animal protein, with the exception of fishmeal, must have been submitted to any of processing methods 1 to 5 or processing method 7, as set out in Chapter III of Annex IV.
- 3. Fishmeal must have been submitted to:
- (a) any of the processing methods set out in Chapter III of Annex IV; or
- (b) another method which ensures that the product complies with the microbiological standards for derived products set in Chapter I of this Annex.
- C. Storage
- 1. Processed animal protein must be packed and stored in new or sterilised bags or stored in properly constructed bulk bins or in storage sheds.

Sufficient measures must be taken to minimise condensation inside bins, conveyors or elevators.

- 2. Products in conveyors, elevators and bins must be protected from casual contamination.
- 3. Equipment for handling processed animal protein must be maintained in a clean and dry condition and must have adequate inspection points so that equipment can be examined for cleanliness.

All storage facilities must be emptied and cleaned regularly, to the extent necessary to prevent contamination.

4. Processed animal protein must be kept dry.

Leakages and condensation in the storage area must be prevented.

#### Section 2

#### Specific requirements for blood products

#### A. Raw material

Only blood referred to in Article 10(a) and Article 10(b)(i) of Regulation (EC) No 1069/2009 may be used for the production of blood products.

B. Processing standards

Blood products must have been submitted to:

- (a) any of the processing methods 1 to 5 or processing method 7, as set out in Chapter III of Annex IV; or
- (b) another method which ensures that the blood product complies with the microbiological standards for derived products set out in Chapter I of this Annex.

#### Section 3

# Specific requirements for rendered fats, fish oil and fat derivatives from Category 3 material

- A. Raw materials
- [<sup>F3</sup>]. Rendered fats

Only Category 3 material, other than Category 3 materials referred to in Article 10(n), (o) and (p) of Regulation (EC) No 1069/2009, may be used for the production of rendered fat.]

2. Fish oil

Only Category 3 material referred to in Article 10(i) and (j) of Regulation (EC) No 1069/2009 and Category 3 material of aquatic animal origin referred to in Article 10(e) and (f) of that Regulation may be used for the production of fish oil.

B. Processing standards

Unless the fish oil or rendered fats have been produced in accordance with Sections VIII or XII of Annex III to Regulation (EC) No 853/2004, respectively, rendered fats must be produced using any of the processing methods 1 to 5 or processing method 7, and fish oils may be produced:

- (a) using processing methods 1 to 7, as set out in Chapter III of Annex IV; or
- (b) in accordance with another method which ensures that the product complies with the microbiological standards for derived products set out in Chapter I of this Annex.

Rendered fats derived from ruminant animals must be purified in such a way that the maximum level of remaining total insoluble impurities does not exceed 0,15 % in weight.

Fat derivatives from Category 3 rendered fats or fish oil shall be produced in accordance with one of the processing methods referred to in Chapter III of Annex IV.

C. Hygiene requirements

Where rendered fat or fish oil is packaged, it must be packaged in new containers or in containers that have been cleaned and disinfected if necessary for the prevention of contamination and all precautions must be taken to prevent its recontamination.

Where bulk transport of those products is intended, the pipe, pumps and bulk tanks and any other bulk container or bulk road tanker used in the transportation of the products from the manufacturing plant either directly on to the ship or into shore tanks or directly to plants must be clean before use.

## Section 4

# Specific requirements for milk, colostrum and certain other products derived from milk or colostrum

#### Part I

## General requirements

## A. Raw material

Only milk referred to in Article 10(e) of Regulation (EC) No 1069/2009, other than centrifuge or separator sludge, and milk referred to in Article 10(f) and (h) of Regulation (EC) No 1069/2009 may be used for the production of milk, milk-based products and milk-derived products.

Colostrum may only be used provided that it originates from live animals that did not show any signs of disease communicable through the colostrum to humans or animals.

- B. Processing standards
- 1. Milk must be subjected to one of the following treatments:
- 1.1. sterilisation at an  $F_0^{(5)}$  value of three or more;
- 1.2. UHT<sup>(6)</sup> combined with one of the following:
  - (a) a subsequent physical treatment, by:
    - (i) a drying process, combined in the case of milk intended for feeding with additional heating to 72 °C or more; or
    - (ii) lowering the pH below 6 for at least 1 hour;
  - (b) the condition that the milk, milk-based product or milk-derived product has been produced at least 21 days before shipping and that during that period no case of foot-and-mouth disease has been detected in the Member State of origin;
- 1.3.  $HTST^{(7)}$  applied twice;
- 1.4. HTST in combination with one of the following:
  - (a) a subsequent physical treatment, by:
    - (i) a drying process, combined in the case of milk intended for feeding with additional heating to 72 °C or more; or

- (ii) lowering the pH below 6,0 for at least 1 hour;
- (b) the condition that the milk, milk-based product or milk-derived product has been produced at least 21 days before shipping and that during that period no case of foot-and-mouth disease has been detected in the Member State of origin.
- 2. Milk-based products and milk-derived products must either be subjected to at least one of the treatments provided for in point 1 or be produced from milk treated in accordance with point 1.
- 3. Whey to be fed to animals of species susceptible to foot-and-mouth disease and produced from milk treated in accordance with point 1 must:
- (a) either be collected at least 16 hours following milk clotting and its pH must be recorded as below 6,0 before transport to animal holdings; or
- (b) have been produced at least 21 days before shipping and during that period no case of foot-and-mouth disease has been detected in the Member State of origin.
- 4. In addition to the requirements set out in points 1, 2 and 3, milk, milk-based products and milk-derived products must meet the following requirements:
- 4.1. after completion of the processing, every precaution must be taken to prevent contamination of the products;
- 4.2. the final product must be labelled so as to indicate that it contains Category 3 material and is not intended for human consumption, and it must be:
  - (a) packed in new containers; or
  - (b) transported in bulk in containers or other means of transport that before use were thoroughly cleansed and disinfected.
- 5. Raw milk must be produced under conditions offering adequate guarantees as regards animal health.
- 6. Colostrum and colostrum products must:
- 6.1. be obtained from bovine animals kept on a holding on which all bovine herds are recognised as officially tuberculosis-free, officially brucellosis-free and officially enzootic-bovine-leukosis-free as defined in Article 2(2)(d), (f) and (j) of Directive 64/432/EEC;
- 6.2. have been produced at least 21 days before shipping and during that period no case of foot-and-mouth disease has been detected in the Member State of origin;
- 6.3. have undergone a single HTST treatment<sup>(7)</sup>;
- 6.4. comply with the requirements set out in point 4 of this Part.

#### Part II

#### Derogation for the placing on the market of milk processed in accordance with national standards

- [<sup>F1</sup>]. The requirements laid down in points 2 and 3 of this Part shall apply to the processing, use and storage of milk, milk-based products and milk-derived products which are Category 3 material, as referred to in Article 10(e) of Regulation (EC) No 1069/2009, other than centrifuge or separator sludge, and milk, milk-based products and milk-derived products referred to in Article 10(f) and (h) of that Regulation, that have not been processed in accordance with Part I of this Section.]
- 2. The competent authority shall authorise milk processing establishments approved or registered in accordance with Article 4 of Regulation (EC) No 853/2004 to supply milk, milk-based products and milk-derived products for the purposes referred to in point 3 of this Part provided the establishment concerned ensures the traceability of the products.
- 3. Milk, milk-based products and milk-derived products may be supplied and used as feed material:
- (a) in the Member State concerned and in cross-border areas where the Member States concerned have a mutual agreement to that effect, in the case of derived products, including white water, which have been in contact with raw milk and/or milk pasteurised in accordance with the requirements for heat treatment set out in point II.1(a) or (b) of Chapter II of Section IX of Annex III to Regulation (EC) No 853/2004, if those derived products have been subject to one of the following treatments:
  - (i) UHT;
  - (ii) sterilisation whereby either an Fc value equal or greater than 3 is achieved, or which was carried out at a temperature of at least 115 °C for 15 minutes or an equivalent combination of temperature and time;
  - (iii) pasteurisation or sterilisation, other than that referred to in point (ii), followed by:
    - in the case of dried milk or dried milk-based products or milkderived products, a drying process;
    - in the case of an acidified milk product, a process by which the pH is reduced and kept for at least one hour at a level below 6;
- (b) in the Member State concerned,
  - (i) in the case of derived products, including white water, which have been in contact with milk that has only been pasteurised in accordance with the requirements for heat treatment set out in point II.1 (a) of Chapter II of Section IX of Annex III to Regulation (EC) No 853/2004, and whey produced from non heat-treated milk-based products, which has been collected at least 16 hours after milk clotting and where the pH must be recorded as < 6,0 before supplying the whey for feeding, provided that they are sent to a limited number of authorised animal holdings, fixed on the basis of the risk assessment for the best and worst case scenarios carried out by the Member State concerned in preparation of the contingency plans for epizootic diseases, in particular foot-and-mouth disease;

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- (ii) in the case of raw products, including white water that has been in contact with raw milk and other products for which the treatments referred to in point (a) and point (b)(i) cannot be ensured, provided that they are sent to a limited number of authorised animal holdings, fixed on the basis of a risk assessment for the best and worst case scenarios carried out by the Member State concerned in preparation of the contingency plans for epizootic diseases, in particular foot-and-mouth disease, and provided that the animals present in the authorised animal holdings can only be moved
  - either directly to a slaughterhouse located in the same Member State, or
  - to another holding in the same Member State, for which the competent authority guarantees that animals susceptible to footand-mouth disease may leave the holding only either directly to a slaughterhouse located in the same Member State, or if the animals have been dispatched to a holding not feeding the products referred to in this point (ii), after a 21-day standstill period has elapsed from the introduction of the animals.
- 4. The competent authority may authorise the supply of colostrum which does not comply with the conditions set out in point B.6 of Part I from one farmer to another farmer within the same Member State for feeding purposes, under conditions which prevent the transmission of health risks.

#### Part III

## Special requirements for centrifuge or separator sludge

Category 3 material comprising of centrifuge or separator sludge must have been subjected to a heat treatment of at least 70 °C for 60 minutes or of at least 80 °C for 30 minutes, before it may be placed on the market for feeding to farmed animals.

 $[^{F4}$ By way of derogation from the first paragraph, the competent authority may authorise alternative parameters for the heat treatment of centrifuge or separator sludge destined for uses within Member States which have authorised those alternative parameters, provided operators can demonstrate that the heat treatment according to the alternative parameters guarantees at least the same risk reduction as the treatment carried out according to the parameters set out in the first paragraph.]

## Section 5

## Specific requirements for gelatine and hydrolysed protein

## A. Raw materials

Only animal by-products which are Category 3 material or products which are derived from such animal by-products, other than materials referred to in Article 10(m), (n), (o) and (p) of Regulation (EC) No 1069/2009 may be used for the production of gelatine and hydrolysed protein.

B. Processing standards for gelatine

1. Unless the gelatine has been produced in accordance with Section XIV of Annex III to Regulation (EC) No 853/2004, it must be produced by a process that ensures that Category 3 material is subjected to a treatment with acid or alkali, followed by one or more rinses.

The pH must be adjusted subsequently. Gelatine must be extracted by heating one or several times in succession, followed by purification by means of filtration and sterilisation.

- 2. After having been subjected to the processes referred to in point 1, gelatine may undergo a drying process and, where appropriate, a process of pulverisation or lamination.
- 3. The use of preservatives, other than sulphur dioxide and hydrogen peroxide, shall be prohibited.
- C. Other requirements for gelatine

Gelatine must be wrapped, packaged, stored and transported under satisfactory hygiene conditions.

In particular:

- (a) a room or a dedicated place must be provided for storing materials for wrapping and packaging;
- (b) wrapping and packaging must take place in a room or in a place intended for that purpose.
- D. Processing standards for hydrolysed protein

Hydrolysed protein must be produced using a production process involving appropriate measures to minimise contamination. Hydrolysed protein derived from ruminants shall have a molecular weight below 10 000 Dalton.

In addition to the requirements of the first paragraph, hydrolysed proteins entirely or partly derived from ruminants' hides and skins shall be produced in a processing plant dedicated only to hydrolysed protein production, using a process involving the preparation of raw Category 3 material by brining, liming and intensive washing followed by exposure of the material to:

- (a) a pH of more than 11 for more than three hours at a temperature of more than 80 °C and subsequently by heat treatment at more than 140 °C for 30 minutes at more than 3,6 bar; or
- (b) a pH of 1 to 2, followed by a pH of more than 11, followed by heat treatment at 140 °C for 30 minutes at 3 bar.

## Section 6

#### Specific requirements for dicalcium phosphate

A. Raw materials

Only animal by-products which are Category 3 material or products which are derived from such animal by-products, other than materials referred to in Article 10(m), (n), (o) and (p) of Regulation (EC) No 1069/2009 may be used for the production of dicalcium phosphate.

- B. Processing standards
- 1. Dicalcium phosphate must be produced by a process that comprises the three following stages:
- (a) firstly, ensures that all bone that is Category 3 material is finely crushed and degreased with hot water and treated with dilute hydrochloric acid (at a minimum concentration of 4 % and a pH of less than 1,5) over a period of at least two days;
- (b) secondly, following the part of the process referred to in point (a), applies a treatment of the obtained phosphoric liquor with lime, resulting in a precipitate of dicalcium phosphate at pH 4 to 7;
- (c) finally, air-dries the precipitate of dicalcium phosphate with inlet temperature of 65 °C to 325 °C and end temperature between 30 °C and 65 °C.
- 2. Where dicalcium phosphate is derived from defatted bones, it shall be derived from bones referred to in Article 10(a) of Regulation (EC) No 1069/2009.

#### Section 7

#### Specific requirements for tricalcium phosphate

#### A. Raw materials

Only animal by-products which are Category 3 material or products which are derived from such animal by-products, other than materials referred to in Article 10(m), (n), (o) and (p) of Regulation (EC) No 1069/2009 may be used for the production of tricalcium phosphate.

B. Processing standards

Tricalcium phosphate must be produced by a process that ensures:

- (a) that all bone that is Category 3 material is finely crushed and degreased in counterflow with hot water (bone chips must be less than 14 mm);
- (b) continuous cooking with steam at 145 °C during 30 minutes at 4 bars;
- (c) separation of the protein broth from the hydroxyapatite (tricalcium phosphate) by centrifugation;
- (d) granulation of the tricalcium phosphate after drying in a fluidised bed with air at 200 °C.

## Section 8

## Specific requirements for collagen

## A. Raw materials

Only animal by-products which are Category 3 material or products which are derived from such animal by-products, other than materials referred to in Article 10(m), (n), (o) and (p) of Regulation (EC) No 1069/2009 may be used for the production of collagen.

B. Processing standards

1. Unless the collagen has been produced in accordance with the requirements for collagen set out in Section XV of Annex III to Regulation (EC) No 853/2004, it must be produced by a process ensuring that unprocessed Category 3 material is subjected to a treatment involving washing, pH adjustment using acid or alkali followed by one or more rinses, filtration and extrusion.

After that treatment collagen may undergo a drying process.

- 2. The use of preservatives, other than those permitted under Union legislation shall be prohibited.
- C. Other requirements

Collagen must be wrapped, packaged, stored and transported under satisfactory hygiene conditions. In particular:

- (a) a room or a dedicated place must be provided for storing materials for wrapping and packaging;
- (b) wrapping and packaging must take place in a room or in a place intended for that purpose.

#### Section 9

#### **Specific requirements for egg products**

A. Raw materials

Only animal by-products referred to in Article 10(e) and (f) and Article 10(k)(ii) of Regulation (EC) No 1069/2009 may be used for the production of egg products.

B. Processing standards

Egg products must have been:

- (a) submitted to any of the processing methods 1 to 5 or processing method 7 set out in Chapter III of Annex IV;
- (b) submitted to another method and parameters which ensure that the products comply with the microbiological standards for derived products set out in Chapter I; or
- (c) treated in accordance with the requirements for eggs and egg products set out in Chapters I, II and III of Section X of Annex III to Regulation (EC) No 853/2004.

# *<sup>F1</sup>Section* 10

# Specific requirements for feeding to farmed animals, other than fur animals, of certain Category 3 material referred to Article 10(f) of Regulation (EC) No 1069/2009

Category 3 material comprising of foodstuffs containing products of animal origin originating from Member States which are no longer intended for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arise, referred to in Article 10(f) of Regulation (EC) No 1069/2009, may be placed on the market for feeding to farmed animals, other than fur animals, without further treatment, provided that the material:

<i>Status:</i> Point in time view as at 23/02/2015.	
<b>Changes to legislation:</b> There are currently no known outstanding effects for the	
Commission Regulation (EU) No 142/2011. (See end of Document for details)	

- (i) has undergone processing as defined in Article 2(1)(m) of Regulation (EC) No 852/2004 or in accordance with this Regulation;
- (ii) is composed of or contain one or more of the following Category 3 materials referred to in Article 10(f) of Regulation (EC) No 1069/2009:
  - milk,
  - milk-based products,
  - milk-derived products,
  - eggs,
  - egg products,
  - honey,
  - rendered fats,
  - collagen,
  - gelatine;
- (iii) has not been in contact with any other Category 3 materials; and
- (iv) all necessary precautions have been taken to prevent the contamination of the material.]

## CHAPTER III

## **REQUIREMENTS FOR CERTAIN FISH FEED AND FISHING BAITS**

- 1. Animal by-products from fish or aquatic invertebrates and derived products therefrom that are intended as feed for farmed fish or for other aquaculture species shall:
- (a) be handled and processed separately from material not authorised for that purpose;
- (b) originate
  - (i) from wild fish or other aquatic animals, except sea mammals, landed for commercial purposes, or from animal by-products from wild fish originating in plants manufacturing fish products for human consumption; or
  - (ii) from farmed fish, provided it is fed to farmed fish of another species;
- (c) be processed in a processing plant in accordance with a method which ensures a microbiologically safe product, including with regard to fish pathogens.
- 2. The competent authority may lay down conditions, aimed at preventing unacceptable risks for the transmission of diseases communicable to humans or animals, for the use of aquatic animals and of aquatic and terrestrial invertebrates:
- (a) as feed for farmed fish or for aquatic invertebrates, when the animal by-products have not been processed in accordance with point 1(c);
- (b) as fishing bait, including bait for aquatic invertebrates.

#### ANNEX XI

#### ORGANIC FERTILISERS AND SOIL IMPROVERS

#### CHAPTER I

#### **REQUIREMENTS FOR UNPROCESSED MANURE, PROCESSED MANURE AND DERIVED PRODUCTS FROM PROCESSED MANURE**

#### Section 1

#### **Unprocessed manure**

- 1. Trade in unprocessed manure of species other than poultry or equidae between Member States shall be subject to the following conditions, in addition to the consent of the Member State of destination referred to in Article 48(1) of Regulation (EC) No 1069/2009:
- (a) Trade in unprocessed manure of species other than poultry or equidae shall be prohibited, except for manure:
  - (i) from an area which is not subject to restrictions by virtue of a serious transmissible disease; and
  - (ii) intended for application, under the supervision of the competent authorities, to land forming part of a single holding located on both sides of the border of two Member States.
- (b) However, the competent authority of the Member State of destination may, having regard to the origin of the manure, its destination and health considerations, grant specific authorisation for the introduction on to its territory of:
  - (i) manure intended for:
    - processing in a plant for the manufacture of derived products which are destined for uses outside the feed chain, or
      - transformation into biogas or composting in accordance with Regulation (EC) No 1069/2009 and with Annex V to this Regulation with a view to the manufacture of the products referred to in Section 2 of this Chapter.

In those cases, the competent authority shall take account of the origin of the manure when authorising the introduction to such plants; or

- (ii) manure intended for applying to land on a holding, provided that the competent authority of the Member State of origin has communicated its agreement to such trade.
- (c) in the cases referred to in point (b), a health attestation in accordance with the model set out in point 3 shall be added to the commercial document which accompanies the consignment of manure.
- 2. Trade in unprocessed poultry manure between Member States shall be subject to the following conditions, in addition to the consent of the Member State of destination referred to in Article 48(1) of Regulation (EC) No 1069/2009:

- (a) the manure must originate in an area which is not subject to restrictions by virtue of Newcastle disease or avian influenza;
- (b) in addition, unprocessed manure from poultry flocks vaccinated against Newcastle disease must not be dispatched to a region which has obtained Newcastle disease non-vaccinating status pursuant to Article 15(2) of Directive 2009/158/EC; and
- (c) a health attestation in accordance with the model set out in point 3 shall be added to the commercial document which accompanies the consignment of manure.
- 3. Model health attestation to be added to the commercial document:

Status: Point in time view as at 23/02/2015.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011. (See end of Document for details)

EURO	OPEA	N UNION	Commercial docu	nen
	l.1.	Consignor	I.2. Document reference No I.2.a. Local reference No	
		Name	I.3. Central competent authority	
		Address Postcode	I.4. Local competent authority	
nent	1.5.	Consignee	1.6.	
ignm		Name		
onsi		Address		
o pe		Postcode	1.7.	
tche		Tel.		
Part I: Details of dispatched consignment	1.8.	Country of origin ISO code I.9. Region of origin Code	I.10. Country of ISO I.11. Region of Coo destination code destination	le
Details	1.12.	Place of origin	I.13. Place of destination	
		Establishment	Establishment D Other	
Par		Name Approval number Address	Name Approval number Address	
		Postcode	Postcode	
	l.14.	Place of loading	I.15. Date of departure	
	l.16.	Means of transport	I.17. Transporter	
		Aeroplane 🗌 Ship 🗋 Railway wagon 🗌	Name Approval number Address	
		Road vehicle Other	Postcode Member State	
		Identification		
	I.18.	Description of commodity	I.19. Commodity code (HS code)	
			I.20. Quantity	
	1.21.	Temperature of products	I.22. Number of packages	
		Ambient Chilled	Frozen	
	1.23.	Seal/Container No	I.24. Type of packaging	
	1.25.	Commodities certified for:		
		Technical use		
	I.26. Transit through third country		I.27. Transit through Member States	
		Third country ISO code	Member State ISO code	
		Exit point Code Entry point BIP unit No	Member State ISO code Member State ISO code	
	1.28.	Export	1.29.	_
		Third country ISO code		
		Exit point Code		
	1.30.			
	1.31.	Identification of the commodities		
		Densite Nature of a survey the Co	Approval number of establishments	_
		Species Nature of commodity Category (scientific name)	Treatment type Manufacturing plant Batch numbe	r

cou	JNTRY	Animal by-pro	oducts/derived products not i	ntended for human consumption
	П.	Health information II.a. C	Certificate reference No	II.b.
	ш.	Health attestation		
I, the undersigned official veterinarian, declare that I understand that the competent authority of the place of destination h to the introduction of the unprocessed manure on its territory and that the unprocessed manure referred to in box refe with the following conditions:				
2	(a) in case of unprocessed poultry manure ( <sup>1</sup> ):			
The manure originates from an area which is not subject to restrictions by virtue of Newcastle disease			castle disease or avian influenza.]	
Image: Structure of the manure originates from an area which is not subject to restrictions by virtue of Newcastle disease or avian and [In the case of unprocessed manure from poultry flocks vaccinated against Newcastle disease, the manure is not disparent region which has obtained Newcastle disease non-vaccinating status pursuant to Article 15(2) of Directive 2009/158/E         (b) in case of unprocessed manure of species other than poultry or equidae ( <sup>1</sup> ):				
Part		(b) in case of unprocessed manure of species other than poultry or eq	uidae ( <sup>1</sup> ):	
		[The manure originates from an area which is not subject to re	estrictions by virtue of a serious	transmissible disease.]
		and		
		either [The manure is intended for processing in a plant for outside the feed chain or manure intended for transforma No 1069/2009 with a view to the manufacture of proces	ation into biogas or composting i	n accordance with Regulation (EC)
		or [The manure is intended for applying to land on a holding	ng.]	
	Notes	s		
	Part I	l:		
	— Во	lox reference I.9 and I.11: if appropriate.		
	— Во	tox reference I.12, I.13 and I.17: approval number or registration number.		
	— Во	lox reference I.14: complete if different from 'I.1. Consignor'.		
	— Во	tox reference I.25: technical use: any use other than for animal consumption	on.	
	— Во	lox reference I.31:		
	Na	Nature of commodity: 'manure'.		
	Part I	11:		
	( <sup>1</sup> ) De	Delete as appropriate.		
	Officia	ial veterinarian/Official inspector		
	Na	lame (in capital letters): Qual	ification and title:	
	Da	Date: Signa	ature:	
	Sta	stamp:		

- 4. Unprocessed manure of equidae may be traded between Member States, provided that the Member State of destination has given its consent to the trade as referred to in Article 48(1) of Regulation (EC) No 1069/2009, and provided it does not originate from a holding subject to animal health restrictions pertaining to glanders, vesicular stomatitis, anthrax or rabies in accordance with Article 4(5) of Directive 2009/156/EC.
- 5. In accordance with Article 48(1)(c)(ii) of Regulation (EC) No 1069/2009, the competent authority of the Member State of destination may require operators dispatching unprocessed manure from another Member State:
- (a) to transmit further information in relation to an intended dispatch, such as precise geographical indications regarding the place where the manure is to be unloaded; and
- (b) to store the manure before application to land.

6. The competent authority may authorise the dispatch of manure transported between two points located on the same farm subject to conditions for the control of possible health risks, such as obligations for the operators concerned to keep appropriate records.

# Section 2

#### Guano from bats, processed manure and derived products from processed manure

[<sup>F5</sup>The placing on the market of processed manure, derived products from processed manure and guano from bats shall be subject to the following conditions. In addition, in the case of guano from bats the consent of the Member State of destination is required as referred to in Article 48(1) of Regulation (EC) No 1069/2009:]

- (a) They must come from a plant for derived products for uses outside the feed chain or from a biogas or a composting plant or from a plant for the manufacturing of organic fertilisers or soil improvers.
- (b) They shall have been subjected to a heat treatment process of at least 70 °C for at least 60 minutes and they shall have been subjected to reduction in spore-forming bacteria and toxin formation, where they are identified as a relevant hazard.
- (c) However, the competent authority may authorise the use of other standardised process parameters than those referred to in point (b), provided an applicant demonstrates that such parameters ensure minimising of biological risks.

That demonstration shall include a validation, which shall be carried out as follows:

- (i) Identification and analysis of possible hazards including the impact of input material, based on a full definition of the processing conditions, and a risk assessment, which evaluates how the specific processing conditions are achieved in practice under normal and atypical situations.
- (ii) Validation of the intended process
  - (ii-1) by measuring the reduction of viability/infectivity of endogenous indicator organisms during the process, where the indicator is:
    - consistently present in the raw material in high numbers,
    - not less heat resistant to the lethal aspects of the treatment process, but also not significantly more resistant than the pathogens for which it is being used to monitor,
    - relatively easy to quantify and relatively easy to identify and confirm; or
  - (ii-2) by measuring the reduction of viability/infectivity, during exposure, of a well-characterised test organism or virus introduced in a suitable test body into the starting material.
- (iii) The validation referred to in point (ii) must demonstrate that the process achieves the following overall risk reduction:
  - for thermal and chemical processes by reduction of *Enterococcus faecalis* by at least 5 log10 and by reduction of infectivity titre of thermoresistant viruses such as *parvovirus*, where they are identified as a relevant hazard, by at least 3 log10,

- for chemical processes also by reduction of resistant parasites such as eggs of *Ascaris* sp. by at least 99,9 % (3 log10) of viable stages.
- (iv) Designing a complete control programme including procedures for monitoring the process.
- (v) Measures ensuring continuous monitoring and supervision of the relevant process parameters fixed in the control programme when operating the plant.

Details on the relevant process parameters used in a plant as well as other critical control points shall be recorded and maintained so that the owner, operator or their representative and the competent authority can monitor the operation of the plant. Information relating to a process authorised under this point must be made available to the Commission on request;

(d) Representative samples of the manure taken during or immediately after processing at the plant in order to monitor the process must comply with the following standards: *Escherichia coli*: n = 5, c = 5, m = 0,  $M = 1\ 000$  in 1 g;

or

*Enterococcaceae*: n = 5, c = 5, m = 0,  $M = 1\ 000$  in 1 g;

and

Representative samples of the manure taken during or on withdrawal from storage at the plant of production or the biogas or composting plant must comply with the following standards:

Salmonella: absence in 25 g: n = 5; c = 0; m = 0; M = 0

where:

n	=	number of samples to be tested;
m	=	threshold value for the number of bacteria; the result is
		considered satisfactory if the number of bacteria in all
		samples does not exceed m;
М	=	maximum value for the number of bacteria; the result
		is considered unsatisfactory if the number of bacteria
		in one or more samples is M or more; and
с	=	number of samples the bacterial count of which may
		be between m and M, the sample still being considered
		acceptable if the bacterial count of the other samples
		is m or less.

Processed manure or processed manure products not complying with the standards in this point shall be regarded as unprocessed;

(e) They must be stored in such a way that once processed contamination or secondary infection and dampness is minimised. They must therefore be stored in:

- (i) well-sealed and insulated silos or properly constructed storage sheds; or
- (ii) properly sealed packs, such as plastic bags or 'big bags'.

#### CHAPTER II

#### REQUIREMENTS FOR CERTAIN ORGANIC FERTILISERS AND SOIL IMPROVERS

#### Section 1

## **Conditions for the production**

- 1. Organic fertilisers and soil improvers, other than manure, digestive tract content, compost, milk, milk-based products, milk-derived products, colostrum, colostrum products and digestion residues from the transformation of animal by-products or derived products into biogas, shall be produced by:
- (a) applying processing method 1 (pressure sterilisation), when Category 2 material is used as starting material;
- (b) [<sup>F1</sup>using processed animal protein, including processed animal protein produced in accordance with point B.1(b)(ii) of Section 1 of Chapter II of Annex X, which has been produced from Category 3 material in accordance with Section 1 of Chapter II of Annex X, or materials which have been subject to another treatment, where such materials may be used for organic fertilisers and soil improvers in accordance with this Regulation; or]
- (c) by applying any of the processing methods 1 to 7, as set out in Chapter III of Annex IV, when Category 3 material is used as starting material which is not used for the production of processed animal protein.
- 2. Organic fertilisers and soil improvers which consist of or which have been produced from meat-and-bone meal derived from Category 2 material or from processed animal protein, shall be mixed, in a registered establishment or plant, with a sufficient minimum proportion of a component which is authorised by the competent authority of the Member State where the product is to be applied to land, in order to exclude the subsequent use of the mixture for feeding purposes.
- 3. The competent authority shall authorise the component referred to in point 2 according to the following:
- (a) the component shall consist of lime, manure, urine, compost or digestion residues from the transformation of animal by-products into biogas or other substances, such as mineral fertilisers, which are not used in animal feed and which exclude the subsequent use of the mixture for feeding purposes according to good agricultural practice;
- (b) the component shall be determined based on an assessment of the climatic and soil conditions for the use of the mixture as a fertiliser, on indications that the component renders the mixture unpalatable to animals or it is otherwise effective in preventing misuse of the mixture for feeding purposes and in accordance with the requirements laid down in Union legislation or, where applicable, national legislation, for the protection of the environment regarding the protection of soil and groundwater.

The competent authority shall make the list of the authorised components available to the Commission and to other Member States upon request.

4. However, the requirements referred to in point 2 shall not apply:

<i>Status:</i> Point in time view as at 23/02/2015.
<b>Changes to legislation:</b> There are currently no known outstanding effects for the
Commission Regulation (EU) No 142/2011. (See end of Document for details)

- (a) to organic fertilisers and soil improvers which are in ready-to-sell packages of not more than 50 kg in weight for use by the final consumer; or
- (b) to organic fertilisers and soil improvers in big bags of not more than 1 000 kg in weight, on the packages of which it is indicated that the organic fertilisers are not destined to land to which farmed animals have access, provided that the competent authority of the Member State where the organic fertiliser or soil improver is to be applied to land, has authorised the use of such big bags on the basis of an assessment of the likelihood of a potential diversion of the materials to farms keeping animals or to land to which farmed animals have access.
- 5. Producers of organic fertilisers and soil improvers must ensure that decontamination of pathogens is carried out prior to their placing on the market, in accordance with:
- Chapter I of Annex X, in the case of processed animal protein or derived products from Category 2 or Category 3 material,
- Section 3 of Chapter III of Annex V in the case of compost and digestion residues from the transformation of animal by-products or derived products into biogas.

## Section 2

#### Storage and transport

After processing or transformation, organic fertilisers and soil improvers shall be properly stored and transported:

- (a) in bulk, under appropriate conditions that prevent contamination;
- (b) packaged or in big bags, in the case of organic fertilisers or soil improvers destined for sale to final users; or
- (c) in the case of storage on farm, in an adequate storage space to which no farmed animals have access.

# [<sup>F4</sup>Section 3

## **Requirements for approval of establishments or plants**

In order to be approved in accordance with Article 24(1)(f) of Regulation (EC) No 1069/2009, operators shall ensure that establishments or plants carrying out the activities referred to in point 1 of Section 1 meet the requirements laid down in Article 8 of this Regulation and:

- (a) have adequate facilities for storage of incoming ingredients to prevent crosscontamination and avoid contamination during storage;
- (b) dispose of unused animal by-products or derived products in accordance with Articles 13 and 14 of Regulation (EC) No 1069/2009.]

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## ANNEX XII

## **INTERMEDIATE PRODUCTS**

In accordance with Article 34(2) of Regulation (EC) No 1069/2009, the following conditions shall apply to the importation and transit through the Union of intermediate products:

- 1. The import and transit of intermediate products shall be authorised, provided that:
  - (a) they are derived from the following materials:
    - (i) Category 3 material, other than materials referred to in Article 10(c), (n), (o) and (p) of Regulation (EC) No 1069/2009;
    - (ii) products generated by the animals referred to in Article 10(i), (l) and (m) of Regulation (EC) No 1069/2009; or
    - (iii) mixtures of the materials referred to in points (i) and (ii);
  - (b) in the case of intermediate products destined for the production of medical devices, in vitro diagnostic medical devices and laboratory reagents, they are derived from:
    - (i) materials which fulfil the criteria referred to in point (a), except that they may have originated from animals which have been submitted to illegal treatment as defined in Article 1(2)(d) of Directive 96/22/ EC or Article 2(b) of Directive 96/23/EC;
    - (ii) Category 2 material referred to in Article 9(f) and (h) of Regulation (EC) No 1069/2009; or
    - (iii) mixtures of the materials referred to in points (i) and (ii);
  - (c) in the case of intermediate products destined for the production of active implantable medical devices, medicinal products and veterinary medicinal products, they are derived from the materials referred to in point (b), where the competent authority considers the use of such materials justified for the protection of public or animal health;
  - (d) they come from a third country listed as a member of the World Organisation for Animal Health (OIE) in the OIE bulletin;
  - (e) they come from an establishment or plant registered or approved by the competent authority of a third country referred to in point (d), in accordance with the conditions set out in point 2;
  - (f) each consignment is accompanied by a declaration of the importer in accordance with the model declaration set out in Chapter 20 of Annex XV, which must be at least in one of the official languages of the Member State in which the inspection at the border inspection post must be carried out and of the Member State of destination; these Member States may allow the use of other languages and request official translations for declarations in such other languages;
  - (g) in the case of materials referred to in point (b), the importer demonstrates to the competent authority that the materials:

- (i) do not carry any risk of transmission of a disease communicable to humans or animals; or
- (ii) are transported under conditions which prevent the transmission of any diseases communicable to humans or animals.
- 2. An establishment or plant may be registered or approved by the competent authority of a third country, as referred to in point 1(e), provided that:
  - (a) the operator or owner of the plant or his representative:
    - (i) demonstrates that the plant has adequate facilities for the transformation of the materials referred to in point 1(a), (b) or (c), as applicable, to ensure the completion of the necessary design, transformation and manufacturing stages;
    - (ii) establishes and implements methods of monitoring and checking the critical control points on the basis of the process used;
    - (iii) keeps a record of the information obtained pursuant to point (ii) for a period of at least two years for submission to the competent authority;
    - (iv) informs the competent authority if any available information reveals the existence of a serious animal health or public health risk;
  - (b) the competent authority of the third country carries out, at regular intervals, inspections of the establishment or plant and supervises the plant in accordance with the following conditions:
    - the frequency of inspections and supervision shall depend on the size of the plant, the type of products manufactured, risk assessment and guarantees offered, based on a system of checks which has been set up in accordance with the hazard analysis and critical control points (HACCP) principles;
    - (ii) if the inspection carried out by the competent authority reveals that the provisions of this Regulation are not being complied with, the competent authority shall take appropriate action;
    - (iii) the competent authority shall draw up a list of establishments or plants approved or registered in accordance with this Annex and shall assign an official number to each plant, which identifies the establishment or plant with respect to the nature of its activities; that list and subsequent amendments to it shall be submitted to the Member State where the inspection at the border inspection post must be carried out and to the Member State of destination.
- 3. [<sup>F3</sup>The intermediate products imported into the Union shall be checked at the border inspection post in accordance with Article 4 of Directive 97/78/EC and transported directly from the border inspection post either to:
  - (a) a registered establishment or plant for the production of laboratory reagents, medical devices and *in vitro* diagnostic medical devices for veterinary purposes or the derived products referred to in Article 33 of Regulation (EC)

No 1069/2009, where the intermediate products must be further mixed, used for coating, assembled or packaged before they are placed on the market or put into services in accordance with the Union legislation applicable to the derived product;]

- (b) an establishment or plant which has been approved for the storage of animal by-products in accordance with Article 24(1)(i) of Regulation (EC) No 1069/2009, from where they must only be dispatched to an establishment or plant referred to in (a) of this point for the uses referred to in (a).
- 4. Intermediate products in transit through the Union shall be transported in accordance with Article 11 of Directive 97/78/EC.
- 5. The official veterinarian at the border inspection post concerned shall inform the authority in charge of the establishment or plant at the place of destination of the consignment by means of the TRACES system.
- 6. The operator or owner of the establishment or plant of destination or his representative shall keep records in accordance with Article 22 of Regulation (EC) No 1069/2009 and shall provide the competent authority on request with the necessary details of purchases, sales, uses, stocks and disposals of surplus of the intermediate products for the purposes of checking compliance with this Regulation.
- 7. The competent authority shall ensure, in accordance with Directive 97/78/EC, that the consignments of intermediate products are sent from the Member State where the inspection at the border inspection post must be carried out to the plant of destination, as referred to in point 3 or, in the case of transit, to the border inspection post of exit.
- 8. The competent authority shall carry out documentary checks at regular intervals for the purpose of reconciliation of the quantities of intermediate products imported on the one hand, and stocked, used, dispatched or disposed of on the other, in order to check compliance with this Regulation.
- 9. For consignments of intermediate products in transit, the competent authorities responsible for the border inspection posts of entry and of exit respectively shall cooperate as necessary to ensure that effective checks are carried out and to ensure the traceability of such consignments.

# ANNEX XIII

# PETFOOD AND CERTAIN OTHER DERIVED PRODUCTS

## CHAPTER I

## **General requirements**

Petfood plants and establishments or plants producing derived products referred to in this Annex shall have adequate facilities for:

(a) storing and treating incoming material under conditions which prevent the introduction of risks to public and animal health;

(b) disposing of unused animal by-products and derived products remaining after production, unless the unused material is sent for processing or disposal to another establishment or plant, in accordance with this Regulation.

## CHAPTER II

## Specific requirements for petfood, including dogchews

## 1. Raw petfood

Operators may only manufacture raw petfood from Category 3 material referred to in Article 10(a) and Article 10(b)(i) and (ii) of Regulation (EC) No 1069/2009.

Raw petfood must be packed in new packaging preventing any leakage.

Effective steps must be taken to ensure that the product is not exposed to contamination throughout the production chain and up to the point of sale.

2. Raw material for processed petfood and for dogchews

Operators may manufacture processed petfood and dogchews only from:

- (a) Category 3 material, other than material referred to in Article 10(n), (o) and (p) of Regulation (EC) No 1069/2009; and
- (b) in the case of imported petfood or petfood produced from imported materials, from Category 1 material comprising of animal by-products derived from animals which have been submitted to illegal treatment as defined in Article 1(2)(d) of Directive 96/22/EC or Article 2(b) of Directive 96/23/EC.
- 3. Processed petfood
- (a) Canned petfood must be subjected to heat treatment to a minimum Fc value of 3.
- (b) Processed petfood other than canned petfood must:
  - (i) be subjected to a heat treatment of at least 90 °C throughout the substance of the final product;
  - (ii) be subjected to a heat treatment to at least 90 °C of the ingredients of animal origin; or
  - (iii) be produced as regards feed material of animal origin exclusively using:
    - animal by-products or derived products from meat or meat products which have been subject to a heat treatment of at least 90 °C throughout their substance;
    - the following derived products which have been produced in accordance with the requirements of this Regulation: milk and milk-based products, gelatine, hydrolysed protein, egg products, collagen, blood products referred to in Section 2 of Chapter II of Annex X, processed animal protein including fishmeal, rendered fat, fish oils, dicalcium phosphate, tricalcium phosphate or flavouring innards;

- (iv) if authorised by the competent authority, be subject to a treatment such as drying or fermentation, which ensures that the petfood poses no unacceptable risks to public and animal health;
- (v) in the case of animal by-products referred to in Article 10(1) and (m) of Regulation (EC) No 1069/2009 and in the case of animal by-products generated by aquatic animals, aquatic and terrestrial invertebrates, and if authorised by the competent authority, be subject to a treatment which ensures that the petfood poses no unacceptable risks to public and animal health.

After production, every precaution must be taken to ensure that such processed petfood is not exposed to contamination.

The processed petfood must be packaged in new packaging.

4. Dogchews must be subjected to a treatment that is sufficient to destroy pathogenic organisms, including salmonella.

After that treatment, every precaution must be taken to ensure that such dogchews are not exposed to contamination.

The dogchews must be packed in new packaging.

5.	Random samples must be taken from dogchews and from processed petfood, other
	than from canned petfood and other than from such processed petfood which has been
	treated in accordance in point 3(b)(v), during production and/or during storage (before
	dispatch) to verify compliance with the following standards:
	Salmonella: absence in 25 g, $n = 5$ , $c = 0$ , $m = 0$ , $M = 0$ .
	Enterobacteriaceae: $n = 5$ , $c = 2$ , $m = 10$ , $M = 300$ in 1 g

Where:

n	= number of samples to be tested;	
m	= threshold value for the number of bacteria; the result shall be considered satisfactory if the number of bacteria in all samples does not exceed m;	
Μ	= maximum value for the number of bacteria; the result shall be considered unsatisfactory if the number of bacteria in one or more samples is M or more; and	
c	<ul> <li>number of samples the bacterial count of which may be between m and M, the sample shall still be considered acceptable if the bacterial count of the other samples is m or less.</li> </ul>	
6.	Random samples must be taken from raw petfood during production and/or during storage (before dispatch) to verify compliance with the following standards:	
	Salmonella: absence in 25 g, $n = 5$ , $c = 0$ , $m = 0$ , $M = 0$ .	
	Enterobacteriaceae: $n = 5$ , $c = 2$ , $m = 10$ , $M = 5\ 000$ in 1 g	
Where:		
n	= number of samples to be tested;	
m	= threshold value for the number of bacteria; the result shall be considered satisfactory if the number of bacteria in all samples does not exceed m;	
М	= maximum value for the number of bacteria; the result shall be considered unsatisfactory if the number of bacteria in one or more	

samples is M or more; and

<b>Status:</b> Point in time view as at 23/02/2015.	
Changes to legislation: There are currently no known outstanding effects for the	
Commission Regulation (EU) No 142/2011. (See end of Document for details)	

- с
- = number of samples the bacterial count of which may be between m and M, the sample shall still be considered acceptable if the bacterial count of the other samples is m or less.
- 7. End point for processed petfood and dogchews

The following may be placed on the market without restrictions in accordance with this Regulation:

- (a) processed petfood
  - (i) which has been manufactured and packaged in the Union in accordance with point 3 and which has been tested in accordance with point 5; or
  - (ii) which has been subject to veterinary checks in accordance with Directive 97/78/EC at a border inspection post.
- (b) dogchews
  - (i) which have been manufactured and packaged in the Union in accordance with point 4 and which has been tested in accordance with point 5; or
  - (ii) which have been subject to veterinary checks in accordance with Directive 97/78/EC at a border inspection post.

# CHAPTER III

## Specific requirements for flavouring innards for the manufacture of petfood

- 1. Operators may only use animal by-products which may be used as raw material for processed petfood and dogchews in accordance with point 2 of Chapter II for the production of liquid or dehydrated derived products used to enhance the palatability values of petfood.
- 2. Flavouring innards must have been submitted to a treatment method and parameters, which ensure that the product complies with the microbiological standards set out in point 5 of Chapter II of this Annex. After treatment, every precaution must be taken to ensure that the product is not exposed to contamination.
- 3. The end product must be:
- (a) packed in new or sterilised packaging; or
- (b) transported in bulk in containers or other means of transport that were thoroughly cleaned and disinfected.

## CHAPTER IV

#### Specific requirements for blood and blood products from equidae

The placing on the market of blood and blood products from equidae for purposes other than in feed shall be subject to the following conditions:

1. Blood may be placed on the market for such purposes provided that it has been collected:

- (a) from equidae which:
  - (i) at inspection on the date of blood collection do not show clinical signs of any of the compulsorily notifiable diseases listed in Annex I to Directive 2009/156/EC and of equine influenza, equine piroplasmosis, equine rhinopneumonitis and equine viral arteritis listed in point 4 of Article 1.2.3. of the Terrestrial Animal Health Code of the OIE, 2010 edition;
  - (ii) have been kept for a period of at least 30 days prior to the date of and during blood collection on holdings under veterinary supervision which were not subject to a prohibition order pursuant to Article 4(5) of Directive 2009/156/EC or restrictions pursuant to Article 5 of that Directive;
  - (iii) for the periods laid down in Article 4(5) of Directive 2009/156/EC had no contact with equidae from holdings which were subject to a prohibition order for animal health reasons pursuant to that Article and for a period of at least 40 days prior to the date of and during blood collection had no contact with equidae from a Member State or third country not considered free of African horse sickness in accordance with points (a) and (b) of the first subparagraph of Article 5(2) of that Directive;
- (b) under veterinary supervision either:
  - (i) in slaughterhouses registered or approved in accordance with Regulation (EC) No 853/2004; or
  - (ii) in facilities approved, furnished with a veterinary approval number and supervised by the competent authority for the purpose of collecting blood from equidae for the production of blood products for purposes other than feeding.
- 2. Blood products may be placed on the market for such purposes provided that:
  - (a) all precautions have been taken to avoid contamination of the blood products with pathogenic agents during production, handling and packaging;
  - (b) the blood products have been produced from blood which:
    - (i) either fulfils the conditions set out in point 1(a); or
    - (ii) has been subjected to at least one of the following treatments, followed by an effectiveness check, for the inactivation of possible causative pathogens for African horse sickness, equine encephalomyelitis of all types including Venezuelan equine encephalomyelitis, equine infectious anaemia, vesicular stomatitis and glanders (*Burkholderia mallei*):
      - heat treatment at a temperature of 65 °C for at least three hours,
      - irradiation at 25 kGy by gamma rays,
      - change in pH to pH 5 for two hours,
      - heat treatment of at least 80 °C throughout their substance.

3. Blood and blood products from equidae must be packed in sealed impermeable containers which, in the case of blood from equidae, bear the approval number of the slaughterhouse or facilities of collection referred to in point 1(b).

# CHAPTER V

#### Specific requirements for hides and skins of ungulates and products derived therefrom

#### A. Establishments and plants

The competent authority may authorise plants handling hides and skins, including limed hides, to supply trimmings and splittings of these hides and skins for the production of gelatine for animal consumption, organic fertilisers or soil improvers, provided that:

- (a) the plant has storage rooms with hard floors and smooth walls that are easy to clean and disinfect and, where appropriate, provided with refrigeration facilities;
- (b) the storage rooms are kept in a satisfactory state of cleanliness and repair, so that they do not constitute a source of contamination for the raw materials;
- (c) if raw material not in conformity with this Chapter is stored and/or processed in these premises, it must be segregated from raw material in conformity with this Chapter throughout the period of receipt, storage, processing and dispatch;
- (d) in the case of trimmings and splittings derived from limed hides, the trimmings and splittings are submitted to a treatment which ensures that no risks to public and animal health remain before being used for the production of:
  - (i) gelatine for animal consumption; or
  - (ii) organic fertilisers or soil improvers.
- B. Placing on the market of animal by-products and of derived products
- 1. Untreated hides and skins may be placed on the market subject to the health conditions applicable to fresh meat pursuant to Directive 2002/99/EC.
- 2. Treated hides and skins may be placed on the market, provided that:
- (a) they have not been in contact with other animal products or live animals presenting a risk of spreading a serious transmissible disease;
- (b) the commercial document laid down in Chapter III of Annex VIII contains a statement indicating that all precautions have been taken to avoid contamination with pathogenic agents.
- C. End point for hides and skins
- 1. Hides and skins of ungulates which pursuant to the decision of an operator are destined for purposes other than human consumption, and which comply with the requirements of Regulation (EC) No 853/2004 for raw materials for gelatine or collagen intended for use in food may be placed on the market without restrictions in accordance with this Regulation.
- 2. The following treated hides and skins may be placed on the market without restrictions in accordance with this Regulation:

- (a) hides and skins having undergone the complete process of tanning;
- (b) 'wet blue';
- (c) 'pickled pelts';
- (d) limed hides (treated with lime and in brine at a pH of 12 to 13 for at least eight hours).
- 3. By way of derogation from point C.2, the competent authority may require that consignments of treated hides and skins referred to in point 2(c) and (d) are accompanied by a commercial document in accordance with the model set out under point 6 of Chapter III of Annex VIII, when they are supplied to establishments or plants producing petfood, organic fertilisers or soil improvers or transforming those materials into biogas.

## CHAPTER VI

#### Specific requirements for game trophies and other preparations from animals

- A. The provisions of this Chapter are without prejudice to the measures for the protection of wild fauna, adopted pursuant to Regulation (EC) No 338/97.
- B. Safe sourcing

Game trophies and other preparations from animals, where for the preparation the animal byproducts have been submitted to a treatment or are presented in a state which does not pose any health risks, may be placed on the market, provided they originate from:

- (a) species other than ungulates, birds and animals of the biological class Insecta or Arachnida; and
- (b) animals originating in an area not subject to restrictions as a result of the presence of serious transmissible diseases to which animals of the species concerned are susceptible.
- C. Safe treatment
- 1. Game trophies or other preparations from animals, where for the preparation the animal by-products have been submitted to a treatment or are presented in a state which does not pose any health risks, may be placed on the market, provided they:
- (a) originate from ungulates or birds which have undergone a complete taxidermy treatment ensuring their preservation at ambient temperatures;
- (b) are mounted ungulates or birds or mounted parts of such animals;
- (c) [<sup>F1</sup>have been subject to an anatomical preparation such as by plastination;
- (d) are animals of the biological class Insecta or Arachnida which have been subject to a treatment, such as drying, to prevent any transmission of diseases communicable to humans or animals; or
- (e) are objects in natural history collections or for the promotion of science and they have been:
  - (i) preserved in media, such as alcohol or formaldehyde, which allow display of the items; or

- (ii) embedded completely on micro-slides;
- (f) are processed DNA samples intended for repositories for the promotion of biodiversity research, ecology, medical and veterinary science or biology.]
- 2. Game trophies or other preparations, other than those referred to under points B and C.1, which come from animals originating in an area subject to restrictions as a result of the presence of serious transmissible diseases to which animals of the species concerned are susceptible, may be placed on the market, provided that:
- (a) in the case of game trophies or other preparations solely of bone, horns, hooves, claws, antlers or teeth,
  - (i) they have been immersed in boiling water for an appropriate time so as to ensure that any matter other than bone, horns, hooves, claws, antlers or teeth is removed;
  - (ii) they have been disinfected with a product authorised by the competent authority, in particular with hydrogen peroxide where parts consisting of bone are concerned;
  - (iii) they have been packaged, immediately after treatment, without being in contact with other products of animal origin likely to contaminate them, in individual, transparent and closed packages so as to avoid any subsequent contamination; and
  - (iv) they are accompanied by a health certificate certifying that the conditions set out in (i), (ii) and (iii) have been met;
- (b) in case of game trophies or other preparations consisting solely of hides or skin,
  - (i) they have been:
    - dried,
    - dry- or wet-salted for a period of at least 14 days before the date of dispatch, or
      - subject to a preservation process other than tanning;
  - (ii) they have been packaged, immediately after treatment, without being in contact with other products of animal origin likely to contaminate them, in individual, transparent and closed packages so as to avoid any subsequent contamination; and
  - (iii) they are accompanied by a commercial document or a health certificate certifying that the conditions set out in (i) and (ii) have been met.

## CHAPTER VII

## Specific requirements for wool, hair, pig bristles, feathers, parts of feathers and down

- A. Raw material
- 1. Untreated wool, untreated hair, untreated pig bristles and untreated feathers, parts of feathers and down must be Category 3 materials referred to in Article 10(b) (iii), (iv) and (v) and Article 10(h) and (n) of Regulation (EC) No 1069/2009.

They must be securely enclosed in packaging and dry.

However, in the case of untreated feathers, parts of feathers and down sent directly from the slaughterhouse to the processing plant, the competent authority may allow a derogation from the requirement to dry materials transported on its territory, provided that:

- (a) all necessary measures are taken to avoid any possible spread of disease;
- (b) the transport takes place in waterproof containers and/or vehicles which must be cleaned and disinfected immediately after each use.
- [<sup>F2</sup>2. Movements of pig bristles and wool and hair of animals of the porcine species from regions in which African swine fever is endemic shall be prohibited except for pig bristles and wool and hair of animals of the porcine species that have:]
- (a) been boiled, dyed or bleached; or
- (b) undergone some other form of treatment which is certain to kill pathogenic agents, provided that evidence to this effect is submitted in the form of a certificate from the veterinarian responsible for the place of origin. Factory washing may not be regarded as a form of treatment for the purposes of this provision.
- 3. The provisions of point 1 shall not apply to decorative feathers or feathers:
- (a) carried by travellers for their private use; or
- (b) in the form of consignments sent to private individuals for non-industrial purposes.
- B. End point for wool and hair

Factory-washed wool and hair, and wool and hair which has been treated by another method which ensures that no unacceptable risks remain, may be placed on the market without restrictions in accordance with this Regulation.

Member States may authorise the placing on the market of untreated wool and hair from farms or from establishments or plants which have been registered in accordance with Article 23 of Regulation (EC) No 1069/2009 or approved in accordance with Article 24(1)(i) of the same Regulation on their territory without restrictions in accordance with this Regulation, if they are satisfied that no unacceptable risks to public and animal health arise from the wool and from the hair.

[<sup>F12</sup>Wool and hair produced from animals other than those of the porcine species may be placed on the market without restrictions in accordance with this Regulation, provided:

Textual Amendments		
	Inserted by Commission Regulation (EU) No 1063/2012 of 13 November 2012 amending Regulation (EU) No 142/2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the	
	Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (Text with EEA relevance).	
	Council laying down health rules as regards animal by-products and derived products not intended human consumption and implementing Council Directive 97/78/EC as regards certain samples and it	

(a) it has undergone factory-washing which consists of the immersion of the wool and hair in series of baths of water, soap and sodium hydroxide or potassium hydroxide; or

- (b) it is dispatched directly to a plant producing derived products from wool or hair for the textile industry and such wool or hair has undergone at least one of the following treatments:
  - (i) chemical depilation by means of slaked lime or sodium sulphide;
  - (ii) fumigation in formaldehyde in a hermetically sealed chamber for at least 24 hours;
  - (iii) industrial scouring which consists of the immersion of wool and hair in a water-soluble detergent held at 60-70 °C;
  - (iv) storage, which may include the journey time, at 37 °C for eight days, 18 °C for 28 days or 4 °C for 120 days.]
- C. End point for feathers and down

Feathers, parts of feathers and down which have been factory-washed and treated with hot steam at 100 °C for at least 30 minutes may be placed on the market without restrictions in accordance with this Regulation.

#### CHAPTER VIII

#### Specific requirements for furs

End point

Furs which have been dried at an ambient temperature of 18 °C for two days at a humidity of 55 % may be placed on the market without restrictions in accordance with this Regulation.

#### CHAPTER IX

#### Specific requirements for apiculture by-products

Apiculture by-products intended exclusively for use in apiculture must:

- 1. not come from an area which is subject of a prohibition order associated with an occurrence of:
  - (a) American foulbrood (*Paenibacillus larvae larvae*), except where the competent authority has assessed the risk to be negligible, issued a specific authorisation for use only in that Member State, and taken all other necessary measures to ensure no spread of that disease;
  - (b) acariosis (*Acarapis woodi* (Rennie)), except where the area of destination has obtained additional guarantees in accordance with Article 14(2) of Directive 92/65/EEC;
  - (c) small hive beetle (*Aethina tumida*); or
  - (d) Tropilaelaps mite (*Tropilaelaps* spp.); and
- 2. meet the requirements provided for in Article 8(a) of Directive 92/65/EEC.

Status: Point in time view as at 23/02/2015. Changes to legislation: There are currently no known outstanding effects for the

Commission Regulation (EU) No 142/2011. (See end of Document for details)

# CHAPTER X

# Specific requirements for rendered fats from Category 1 or Category 2 materials for oleochemical purposes

- 1. Rendered fats derived from Category 1 material or from Category 2 material which are destined for oleochemical purposes must be produced using any of the processing methods 1 to 5 as set out in Chapter III of Annex IV.
- 2. Rendered fats derived from ruminant animals must be purified in such a way that the maximum level of remaining total insoluble impurities does not exceed 0,15 % in weight.

# CHAPTER XI

## Specific requirements for fat derivatives

- 1. The following processes may be used to produce fat derivatives from rendered fats derived from Category 1 and Category 2 material:
- (a) transesterification or hydrolysis at least 200 °C, under corresponding appropriate pressure, for 20 minutes (glycerol, fatty acids and esters);
- (b) saponification with NaOH 12M (glycerol and soap):
  - (i) in a batch process at 95 °C for three hours; or
  - (ii) in a continuous process at 140 °C 2 bars (2 000 hPa) for eight minutes; or
- (c) hydrogenation at 160 °C at 12 bars (12 000 hPa) for 20 minutes.
- 2. Fat derivatives produced in accordance with this Chapter may only be placed on the market:
- (a) for uses other than in feed, cosmetics and medicinal products;
- (b) in addition, in the case of fat derivatives from Category 1 material, for uses other than in organic fertilisers and soil improvers.
- [<sup>F11</sup>3. End point for products derived from rendered fats:

Fat derivatives which have been processed as referred to in point 1 may be placed on the market for uses indicated in point 2 without restrictions in accordance with this Regulation.]

# CHAPTER XII

#### Specific requirements for horns and horn products, excluding horn meal, and hooves and hoof products, excluding hoof meal, intended for the production of organic fertilisers or soil improvers

The placing on the market of horns and horn products, excluding horn meal, and hooves and hoof products, excluding hoof meal, intended for the production of organic fertilisers or soil improvers shall be subject to the following conditions:

(a) they must originate from animals that:

- (i) either have been slaughtered in a slaughterhouse, after undergoing an antemortem inspection, and were found fit, as a result of such inspection, for slaughter for human consumption in accordance with Union legislation; or
- (ii) did not show clinical signs of any disease communicable through that product to humans or animals;
- (b) they must have undergone a heat treatment for one hour at a core temperature of at least 80 °C;
- (c) the horns must be removed without opening the cranial cavity;
- (d) at any stage of processing, storage or transport, every precaution shall be taken to avoid cross-contamination;
- (e) they shall be packed either in new packaging or containers; or transported in vehicles or bulk containers which have been disinfected prior to loading using a product approved by the competent authority;
- (f) the packaging or containers must:
  - (i) indicate the type of product (such as horns, horn products, hooves or hoof products);
  - (ii) be marked with the name and address of the approved or registered establishment or plant of destination.

# [<sup>F9</sup>CHAPTER XIII

## Specific requirements for fish oil for the production of medicinal products

End point for fish oil for the production of medicinal products

Fish oil derived from the materials referred to in point A.2 of Section 3 of Chapter II of Annex X, which has been de-acidified with a NaOH solution at a temperature of 80 °C or more and which has subsequently been purified by distillation at a temperature of 200 °C or more, may be placed on the market for the production of medicinal products without restrictions in accordance with this Regulation.]

#### ANNEX XIV

### IMPORTATION, EXPORT AND TRANSIT

#### CHAPTER I

#### SPECIFIC REQUIREMENTS FOR THE IMPORTATION INTO AND TRANSIT THROUGH THE UNION OF CATEGORY 3 MATERIAL AND DERIVED PRODUCTS FOR USES IN THE FEED CHAIN OTHER THAN FOR PETFOOD OR FOR FEED TO FUR ANIMALS

Section As referred to in Article 41(1)(a) and Article 41(3) of Regulation (EC) No 1069/2009, *l* the following requirements shall apply to imported consignments of Category 3 material and derived products therefrom for uses in the feed chain other than for petfood or for feed to fur animals and consignments of such materials and products in transit:

- (a) they must consist of or have been produced from, as applicable, Category 3 material referred to in the column 'raw materials' of Table 1;
- (b) they must comply with the import and transit conditions set out in the column 'import and transit conditions' of Table 1;
- (c) [<sup>F1</sup>they must come from a third country or part of a third country listed in the column 'third countries' list' of Table 1;
- (d) they must come from an establishment or plant which is registered or approved by the competent authority of the third country, as applicable, and which is on the list of such establishments and plants referred to in Article 30; and
- (e) they must be:
  - (i) accompanied during transportation to the point of entry into the Union where the veterinary checks take place by the health certificate referred to in the column 'certificates/model documents' of Table 1; or
  - (ii) presented at the point of entry into the Union where the veterinary checks take place accompanied by a document corresponding to the model referred to in the column 'certificates/model documents' of Table 1.]

(f) 
$$[^{F13}$$
....]

#### **Textual Amendments**

F13 Deleted by Commission Regulation (EU) No 294/2013 of 14 March 2013 amending and correcting Regulation (EU) No 142/2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (Text with EEA relevance).

No	Product	Raw materials (reference to provisions of Regulation (EC) No 1069/2009)	Import and tra conditio	nsit	Third countri lists	es'	Certificates/ model documents
1	[ <sup>F5</sup> processed animal protein, including mixtures	Category 3 materials referred to in Article 10(a), (b), (d), (e),	(a)	The proce anima prote	al	In the case of	Annex XV, Chapter 1.

	and products other than petfood containing such protein, and compound feeds containing such proteins as defined in Article 3(2)(h) of Regulation (EC) No 767/2009]	(f), (h), (i), (j), (k), (l) and (m).	h b p iii a v v S 1 C I I A X a a (b) T p a a (b) T p a s c v v t l a s c c v t l s s c t f l s s t c s t s s t t t s s t s t s t s t	ccordEntited vith countri sectionisted in of 1 of Ar Chapteo Regu I of (EU) N Annex206/20 C; nd (b) The processed nimal proteinThird hall countri omplyisted in vith Annex he to Deci dditi20006/7 equirements et put	n Part inex II ilation o 10. In the case of fishm es n II sion	al ins ding ieal:
2	Blood products for feed material	Category 3 materials referred to in Article 10 (a) and (b)(i).	[ <sup>F3</sup> The bloc products m have been produced i accordance with Sectio 2 of Chapt II of Anne and Sectio 5 of Chapt I of Annex XIV.]	nust <sup>(a)</sup> n e on er x X n third er	f third es n Part inex II ilation o 10, hich s of all	icts

Status: Point in time view as at 23/02/2015.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011. (See end of Document for details)

					fro	e od oducts m er ecies:	
3	Rendered fats and fish oil	(a) (b)	In (a) the case of rendered fats excluding fish oil: Category 3 materials referred to in Article 10(a), (b), (d), (e), (f), (g), (h), (i), (j) and (k). In the case of	in accor with Section 3 of Chap II of Anne X; and The rended fat shall comp with the addit	cas of rer fat exe fisi oil Third needintries listed in Part danteAnnex I to Regulatio o(EU) No 206/2010. ter (b) In ex the cas of fisi oil rEdird countries listed in dannex II to Decision 2006/766/EC	e dered scluding n Annex 2 Chapter (A). I n (b)	In the case of fish oil: XV,

		fish oil: Categ 3 mater referr to in Artic 10(e) (f), (i) and (j).	tials 3 of ed this Chap le			
4	Milk, milk- based products and milk-derived products, colostrum, colostrum products	<ul> <li>(a) Milk, milk- based produ</li> <li>Category</li> <li>3 materials</li> <li>referred to in</li> <li>Article 10(e),</li> <li>(f) and (h).</li> <li>(b) Colos</li> </ul>	products, colostrum and colostrum products shall comply with the requirements set out in Section 4 of this Chapter.	Authorised third countries listed in Annex I to Regulation (EU) No 605/2010. (b) In the case of colo and colo	Annex X Chapter (b)	2(A). In the case of colostrum and colostrums products: XV,
5	Gelatine and hydrolysed protein	Category 3 materials referred to in	The gelatine and the hydrolysed		rd (a) ntries d	In the case

		Article 10(a), (b), (e), (f), (g), (i) and (j), and, in the case of hydrolysed protein: Category 3 materials referred to in Article 10(d), (h) and (k).	protein must have been produced in accordance with Section 5 of Chapter II of Annex X.	Annee II to Regu (EU) No 206/2 and the follow count (KR) South Koree (MY) Mala (PK) Pakis (TW) Taiwa (b) In the case of gelati and	hydrolysed protein: Annex XV, rfegeter 12. ysia tan an.
6	Dicalcium phosphate	Category 3 materials referred to in Article $10(a)$ , (b), (d),(e), (f), (g), (h), (i), (j) and (k).	The dicalcium phosphate must have been produced in accordance with Section 6 of Chapter II of Annex X.	Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010, and the following countries: (KR) South Korea	

				(MY) Mala (PK) Pakis (TW) Taiwa	ysia tan
7	Tricalcium phosphate	Category 3 materials referred to in Article 10(a), (b), (d),(e), (f), (g), (h), (i) and (k).	The tricalcium phosphate must have been produced in accordance with Section 7 of Chapter II of Annex X.	Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010, and the following countries: (KR) South Korea (MY) Malay (PK) Pakis (TW) Taiwa	n a ysia tan
8	Collagen	Category 3 materials referred to in Article 10(a), (b), (e), (f), (g), (i) and (j).	The collagen must have been produced in accordance with Section 8 of Chapter II of Annex X.	Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010, and the following countries: (KR) South Korea (MY) Mala (PK) Pakis (TW) Taiwa	n a ysia tan
9	Egg products	Category 3 materials referred to in Article 10(e), (f) and (k)(ii).	The egg products must have been produced in accordance with Section 9 of Chapter	Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010,	Annex XV, Chapter 15.

	II of Annex X.	and third countries or parts of third countries from which Member States authorise imports of fresh poultrymeat, eggs and egg products, which are listed in Part 1 of Annex I to Regulation (EC) No
		(EC) No 798/2008.

#### Section 2

# [<sup>F5</sup>Imports of processed animal protein, including mixtures and products other than petfood containing such protein, and compound feeds containing such protein as defined in Article 3(2)(h) of Regulation (EC) No 767/2009]

The following requirements shall apply to the importation of processed animal protein:

1. Before consignments are released for free circulation within the Union, the competent authority must sample processed animal protein from imported consignments at the border inspection post to ensure compliance with the general requirements of Chapter I of Annex X.

The competent authority must:

- (a) sample each consignment of products carried in bulk;
- (b) carry out random sampling of consignments of products packaged in the manufacturing plant of origin.
- 2. By way of derogation from point 1, when six consecutive tests on bulk consignments originating in a given third country prove negative, the competent authority of the border inspection post may carry out random sampling of subsequent bulk consignments from that third country.

If one of those random samples proves positive, the competent authority carrying out the sampling must inform the competent authority of the third country of origin so that it can take appropriate measures to remedy the situation.

The competent authority of the third country of origin must bring these measures to the attention of the competent authority carrying out the sampling.

In the event of a further positive result from the same source, the competent authority of the border inspection post must sample each consignment from the same source until six consecutive tests again prove negative.

- 3. Competent authorities must keep a record for at least three years of the results of sampling carried out on all consignments that have undergone sampling.
- 4. Where a consignment imported into the Union proves to be positive for salmonella or where it does not meet the microbiological standards for enterobacteriaceae set out in Chapter I of Annex X, it must either:
  - (a) be dealt with in accordance with the procedure laid down by Article 17(2)
     (a) of Directive 97/78/EC; or
  - (b) reprocessed in a processing plant or decontaminated by a treatment authorised by the competent authority. The consignment must not be released until it has been treated, tested for salmonella or enterobacteriaceae, as necessary, by the competent authority in accordance with Chapter I of Annex X, and a negative result obtained.

#### Section 3

#### **Imports of rendered fats**

The following requirements shall apply to the importation of rendered fats:

Rendered fat shall:

- (a) be entirely or partly derived from porcine raw material and come from a third country or a part of the territory of a third country free from foot-and-mouth disease for the previous 24 months and free from classical swine fever and African swine fever for the previous 12 months;
- (b) be entirely or partly derived from poultry raw material and come from a third country or a part of the territory of a third country free from Newcastle disease and avian influenza for the previous six months;
- (c) be entirely or partly derived from ruminant raw material and come from a third country or a part of the territory of a third country free from foot-and-mouth disease for the previous 24 months and free from rinderpest for the previous 12 months; or
- (d) where there has been an outbreak of one of the diseases referred to in points (a), (b) and (c) during the relevant period referred to in those points, have been subjected to one of the following heat treatments:
  - (i) at least 70 °C for at least 30 minutes; or
  - (ii) at least 90 °C for at least 15 minutes.

Details of the critical control points shall be recorded by operators and maintained so that the owner, operator or their representative and, as necessary, the competent authority can monitor the operation of the plant; and the recorded information shall include the particle size, critical temperature and, as appropriate, the absolute time, pressure profile, raw material feed rate and fat recycling rate.

#### Section 4

#### Imports of milk, milk-based products, milkderived products, colostrum and colostrum products

- A. The following requirements shall apply to the importation of milk, milk-based products, milk-derived products, colostrum and colostrum products:
- 1. Milk, milk-based products and milk-derived products shall:
  - (a) have undergone at least one of the treatments provided for in points 1.1, 1.2, 1.3 and point (a) of point B.1.4 of Part I of Section 4 of Chapter II of Annex X;
  - (b) comply with points B.2 and B.4, and, in the case of whey, point B.3 of Part I of Section 4 of Chapter II of Annex X.
- 2. By way of derogation from point B.1.4 of Part I of Section 4 of Chapter II of Annex X, milk, milk-based products and milk-derived products may be imported from third countries so authorised in column 'A' of Annex I to Regulation (EU) No 605/2010, provided that the milk, milk-based products or milk-derived products have undergone a single HTST treatment and:
  - (a) have not been shipped before a period of at least 21 days has elapsed after production and during that period no case of foot-and-mouth disease has been detected in the exporting third country; or
  - (b) have been presented at a border inspection post of entry into the Union at least 21 days after production and during that period no case of foot-and-mouth disease has been detected in the exporting third country.
- B. The following requirements shall apply to the importation of colostrum and colostrum products:
- 1. The materials shall have undergone a single HTST treatment and:
  - (a) have not been shipped before a period of at least 21 days has elapsed after production and during that period no case of foot-and-mouth disease has been detected in the exporting third country; or
  - (b) have been presented at a border inspection post of entry into the Union at least 21 days after production and during that period no case of foot-and-mouth disease has been detected in the exporting third country.
- 2. The materials shall have been obtained from bovine animals subject to regular veterinary inspections to ensure that they come from holdings on which all bovine herds are:
  - (a) either recognised as officially tuberculosis-free and officially brucellosisfree as defined in Article 2(2)(d) and (f) of Directive 64/432/EEC or not restricted under the national legislation of the third country of origin of the colostrum regarding eradication of tuberculosis and brucellosis; and
  - (b) either recognised as official enzootic-bovine-leukosis-free as defined in Article 2(2)(j) of Directive 64/432/EEC or included in an official system for the control of enzootic bovine leukosis and there has been no evidence as

a result of clinical and laboratory testing of this disease in the herd during the past two years.

- 3. After completion of the processing, every precaution shall have been taken to prevent contamination of the colostrum or colostrum products.
- 4. The final product must bear a label so as to indicate that it contains Category 3 material and is not intended for human consumption, and it must have been:
  - (a) packed in new containers; or
  - (b) transported in bulk in containers or other means of transport that before use were thoroughly cleaned and disinfected.

# *I<sup>F4</sup>Section 5*

# Imports of blood products for the feeding of farmed animals

The following requirements shall apply to the importation of blood products, including spray dried blood and blood plasma which have been derived from porcine animals intended for the feeding of porcine animals:

These derived products must be:

- (a) subjected to a heat treatment at a temperature of at least 80 °C throughout the substance and the dry blood and blood plasma is of not more than 8 % moisture with a water activity (Aw) of less than 0,60;
- (b) stored in dry warehouse conditions under room temperature for at least 6 weeks.]

#### CHAPTER II

#### SPECIFIC REQUIREMENTS FOR THE IMPORTATION INTO AND TRANSIT THROUGH THE UNION OF ANIMAL BY-PRODUCTS AND DERIVED PRODUCTS FOR USES OUTSIDE THE FEED CHAIN FOR FARMED ANIMALS OTHER THAN FUR ANIMALS

#### Section 1

# **Specific requirements**

As referred to in Article 41(1)(a) and (2)(c) and Article 41(3) of Regulation (EC) No 1069/2009, the following specific requirements shall apply to imported consignments of animal by-products and derived products for uses outside the feed chain for farmed animals and consignments of such products in transit:

- (a) they must consist of or have been produced from animal by-products referred to in the column 'raw materials' of Table 2;
- (b) they must comply with the import and transit conditions set out in the column 'import and transit conditions' of Table 2;
- (c) [<sup>F1</sup>they must come from a third country or part of a third country listed in the column 'third countries' list' of Table 2;

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Changes to legislation: There are currently no known outstanding effects for the
Commission Regulation (EU) No 142/2011. (See end of Document for details)

- (d) they must come from an establishment or plant which is registered or approved by the competent authority of the third country, as applicable, and which is on the list of such establishments and plants referred to in Article 30; and
- (e) they must be:
  - (i) accompanied during transportation to the point of entry into the Union where the veterinary checks take place by the health certificate referred to in the column 'certificates/model documents' of Table 2; or
  - (ii) presented at the point of entry into the Union where the veterinary checks take place accompanied by a document corresponding to the model referred to in the column 'certificates/model documents' of Table 2.]
- (f)  $[^{F13}....]$

TABLE 2

No	Product	Raw materials (reference to provisions of Regulation (EC) No 1069/2009)	Import and transit conditions	Third countries' lists	Certificates/ model documents
1	Processed manure, derived products from processed manure and guano from bats	Category 2 material referred to in Article 9(a).	The processed manure, the derived products from processed manure and the guano from bats must have been produced in accordance with Section 2 of Chapter I of Annex XI.	II Ref (E No 200 (b) An I t Do 200 E0 O O C (c) Pa 1 o An I t Ref (E No	of nnex to egulation U) of 06/2010; nnex o ecision 04/211/ C; urt of nnex o egulation C)

2	Blood products, excluding	Category 1 material referred to	The blood products must have been	The following third countries:	(a)	In the
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> Regulation (EU) No 206/2010, in Part 1 of Annex I to Regulation (EC)No 798/2008, or in Part 1 of Annex I to Regulation (EC) No 119/2009. Japan. in the case of treated blood products of any species: Third countries listed in Part 1 to Annex II of Regulation (EU) No 206/2010, in Part 1 of Annex I to Regulation (EC) No

(d)

				798/2008 or in Part 1 of Annex I to Regulation (EC) No 119/2009. Japan.
3	Blood and blood products from equidae	Category 3 materials referred to in Article 10(a), (b), (d) and (h).	The blood and the blood products shall comply with the requirements set out in Section 3.	The following Annex XV, third Chapter 4(A). countries: (a) in the case of blood that has been collected in accordance with point 1 of Chapter IV of Annex XIII or where blood products have been produced in accordance with point 2(b) (i) of that Chapter: Third countries or

> parts of third countries listed in Annex I to Decision 2004/211/ EC, from which the importation of equidae for breeding and production is allowed. in the case of blood products which have been treated in accordance with point 2(b) (ii) of Chapter IV of Annex XIII: Third countries listed in Part 1 of Annex II to

(b)

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4	Fresh or chilled hides and skins of ungulates	Category 3 materials referred to in Article 10 (a) and (b)(iii).	The hides and skins shall comply with the requirements set out in Section 4, points 1 and 4.	The hides and skins come from a third country, or, in the case of regionalisation in accordance with Union legislation, a part of a third country listed in Part 1 of Annex II to Regulation (EU) No 206/2010, from which Member States authorise imports of fresh meat from the same species.	Annex XV, Chapter 5(A)	
5	Treated hides and skins of ungulates	Category 3 materials referred to in Article 10 (a), (b)(i) and (iii) and (n).	The hides and skins shall comply with the requirements set out in Section 4, points 2, 3 and 4.	(a) In the case of treate hides and skins of ungu	hide and skir of	ted es us ulates,

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6	Game trophies and other preparations from animals	Category 2 materials referred to in Article 9, point (f) derived from wild animals not suspected of being infected with a disease communicable to humans or animals and Category 3 material referred to in Article 10(a),	The game trophies and other preparations shall comply with the requirements set out in Section 5.	refern to in Secti 5,	ies rations ed	In the case of game trophies referred to in Section 5, point 2: V,

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7	Pig bristles	Category 3 materials referred to in Article 10 (b) (iv).	The pig bristles must have been obtained from animals originating, and slaughtered in a slaughterhouse in the third country of origin.	(a) In the case of untrea pig bristle Third countries, or, 'in the case of regionalisation regions thereof, listed in part 1 of Annex II to	es:	

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[ <sup>F2</sup> 8	Untreated wool and hair produced from animals other than those of the porcine species	Category 3 materials referred to in Article 10(h) and (n).	(1) (a) (b)	The dry untre wool and hair must be secur enclo in packa and sent direct to a plant produ	(1) ated ely sed aging; tly	Any third count	(1) ry.	For imports of untreated wool and hair, no health certificate is required.

	opera under condi which preve the sprea of patho agent	ing nediate tions, tions n nt ding genic s.		(2)	
(2)	The wool and hair are wool and hair as referr to in Articl 25(2) (e).	ed le	Third countr or region thereo listed in Part 1 of Annex II to Regula (EU) No 206/20 and author for import into the Union of fresh meat of rumina not subjec	y f ation 010 rised ts ants	A declaration of the importer in accordance with Chapter 21 of Annex XV is required.]

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9	Treated feathers, parts of feathers and down	Category 3 materials referred to in Article 10 (b) (v) and (h) and (n).	The treated feathers or parts of feathers shall comply with the requirements set out in Section 6.	Any third country.	For imports of treated feathers, parts of feathers and down, no health certificate is required.

Status: Point in time view as at 23/02/2015.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011. (See end of Document for details)

Apiculture by-products	Category 3 materials referred to in Article 10 (e).	(a)	the case	(a)	In the case	(a)	In the case
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11	Bones and bone products (excluding bone meal), horns and horn products (excluding horn meal) and hooves and hoof products (excluding hoof meal) for uses other than as feed material, organic fertiliser or soil improver	Category 3 materials referred to in Article 10(a) (b)(i) and (iii), (e) and (h).	The products shall comply with the requirements set out in Section 7.	Any third country.	The proc shall be accompa by: (a) (b)	

					one official language of the Member State through which the consignment first enters the Union and in at least one official language of the Member State of destination.
12	Petfood, including dogchews	of	The petfood and the dogchews must have been produced in accordance with Chapter II of Annex XIFF.	(a) In the case of raw petfor Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010 or in Annex I to Regulation (EC) No 798/2008, from which Member States authorise imports of fresh meat from the same species	<ul> <li>(a) In the case of canned</li> <li>od: petfood: Annex XV, Chapter 3(A).</li> <li>(b) In the case of processed petfood other than canned petfood: Annex XV, Chapter 3(B).</li> <li>(c) In the case</li> </ul>

IFI12	Elavouring	Materials	The	and where only bone in meat is authorised. In the case of fish materials, third countries listed in Annex II to Decision 2006/766/EC. (b) In the case of dogcl and petfor other than raw petfor Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010, and the following countries: (JP) Japan (EC) Ecuaa (LK) Sri Lanka (TW) Taiwa	od od: dor a
[ <sup>F1</sup> 13	Flavouring innards for the manufacture of petfood	referred to in Article 35(a)	flavouring innards must have been produced in accordance with Chapter III of Annex XIII.	countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010, from which Member States	Annex XV, Chapter 3(E).]

				authorise imports of fresh mea from the same spe and when only bon in meat i authorise In the cas of flavou innards f fish mate third countries listed in Annex II to Decisi 2006/766 In the cas of flavou innards from pou meat thir countries listed in 1 of Ann to Regula (EC) No 798/2008 from whi Member States authorise imports of fresh pou meat.	of at ccies re e s s d. se ring rom erials, s on 5/EC. se ring lltry d s Part ex I ation 3, ich		
14	Animal by- products for the manufacture of petfood other than raw petfood and of derived products for uses outside the feed chain	[ <sup>F1</sup> (a) (b)	mater	(a) (i)	In the case of anima by- produ for the manu of petfoo In the case	icts facture	

Status: Point in time view as at 23/02/2015.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011. (See end of Document for details)

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	manufacture		by-	the
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			from	
			which	
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		(ii)	Raw	
		(11)	material	
			from	
			poultry	
			including	
			ratites:	
			Third	
			countries	
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> or parts of third countries from which Member States authorise imports of fresh poultrymeat, which are listed in Part 1 of Annex I to Regulation (EC) No 798/2008. Raw material from fish: Third countries listed in Annex II to Decision 2006/766/ EC. Raw material from other wild land mammals and leporidae: Third countries listed in Part

(iii)

(iv)

> 1 of Annex II to Regulation (EU) No 206/2010 or in Part 1 of Annex I to Regulation (EC)No 798/2008. (b) In the case of animal byproducts for the manufacture of pharmaceuticals: Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010, in Part 1 of Annex I to Regulation (EC) No 798/2008 or in Part 1 of Annex I to Regulation (EC) No 119/2009, and the following third countries: (JP) Japan (PH)

> > Philippines

			(TW)
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		(c)	In
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Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011. (See end of Document for details)

				countries listed in Annex II to Decision 2006/766/EC.	
[ <sup>F1</sup> 15	Animal by- products for use as raw petfood	Category 3 materials referred to in Article 10(a) and Article 10(b)(i) and (ii).	The products shall comply with the requirements set out in Section 8.	Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010 or in Annex I to Regulation (EC) No 798/2008, from which Member States authorise imports of fresh meat from the same species and where only bone in meat is authorised. In the case of fish materials, third countries listed in Annex II to Decision 2006/766/EC.	Annex XV, Chapter 3(D).
16	Animal by- products for use in feed for fur animals	Category 3 materials referred to in Article 10(a) to (m)	The products shall comply with the requirements set out in Section 8.	Third countries listed in part 1 of Annex II to Commission Regulation (EU) No 206/2010, or in Annex I to Regulation (EC) No 798/2008, from which Member States	Annex XV, Chapter 3(D).]

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					authorise imports of fresh meat from the same species and where only bone in meat is authorised. In the case of fish materials, third countries listed in Annex II to Decision 2006/766/EC.	
[ <sup>F5</sup> 17	Rendered fats for certain purposes outside the feed chain for farmed animals	[ <sup>F1</sup> (a)	destur for the produ of biodi- or	hemical icts: cories ials ed	Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010 and, in the case of fish materials, third countries listed in Annex II to Decision 2006/766/EC.	Chapter 10(B) of Annex XV.]
		(b)	In the case of mater destin to the			

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[ <sup>F1</sup> 18	Fat	(a)	In	The fat	Any third	(a)	In
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	(b) In the case of fat derive for use as feed: Categ 3 mater referr to in Artic 10. (b) In the case of fat derive for use as feed: Categ 3 mater referr to in Artic 10. (b) In the case of fat derive for use as feed: Categ 3 mater other than mater referr to in Artic 10(n) (o) and (p);	ed le le gory tials ed le atives gory tials tials ed le		as feed: Annex XV, Chapter 14(B).J
Photogelatine	Category 1 materials referred to in Article 8(b) and Category 3 materials referred to in Article 10.	The imported photogelatine shall comply with the requirements set out in Section 11.	Photogelatine may only be imported from establishments of origin in the United States and in Japan that are authorised in	Annex XV, Chapter 19.

19

				accordance with Section 11.	
20	Horns and horn products, excluding horn meal, and hooves and hoof products, excluding hoof meal, for the production of organic fertilisers or soil improvers	Category 3 materials referred to in Article 10(a), (b), (h) and (n).	The products shall comply with the requirements set out in Section 12.	Any third country.	Annex XV, Chapter 18.

#### Section 2

## Imports of blood and blood products, excluding from equidae, for the manufacture of derived products for uses outside the feed chain for farmed animals

The following requirements shall apply to the import of blood and blood products, excluding those from equidae, for the manufacture of derived products for uses outside the feed chain for farmed animals:

- 1. The blood products must originate from a plant for the production of derived products for uses outside the feed chain for farmed animals which meets the specific conditions laid down in this Regulation or from the establishment of collection.
- 2. [<sup>F1</sup>The blood from which blood products for the manufacture of derived products for uses outside the feed chain for farmed animals are produced must have been collected under veterinary supervision:
  - (a) in slaughterhouses:
    - (i) approved in accordance with Regulation (EC) No 853/2004; or
    - (ii) approved and supervised by the competent authority of the country of collection; or
  - (b) from live animals in facilities approved and supervised by the competent authority of the country of collection.]
- 3.1. In the case of blood products for the manufacture of derived products for uses outside the feed chain for farmed animals which have been derived from animals belonging to the taxa Artiodactyla, Perissodactyla and Proboscidea, including their crossbreeds, they must comply with the conditions of either point (a) or (b):
  - (a) the products must have undergone one of the following treatments guaranteeing the absence of pathogens of the diseases referred to in point (b):

- (i) heat treatment at a temperature of 65 °C for at least three hours, followed by an effectiveness check;
  (ii) irradiation at 25 kGy by gamma rays, followed by an effectiveness check;
  (iii) heat treatment of at least 80 °C throughout their substance, followed by an effectiveness check;
  (iv) in the case of animals other than Suidae and Tayassuidae only: change in pH to pH 5 for two hours, followed by an effectiveness check;
  in the case of blood products not treated in accordance with point (a) the products must originate from a third country or region:
  - where no case of rinderpest, peste des petits ruminants and Rift Valley fever has been recorded for a period of at least 12 months and in which vaccination has not been carried out against those diseases for a period of at least 12 months;
  - (ii) where no case of foot-and-mouth disease has been recorded for a period of at least 12 months, and,
    - in which vaccination has not been carried out against this disease for a period of at least 12 months, or
    - in which vaccination programmes against foot-andmouth disease are being officially carried out and controlled in domestic ruminant animals for a period of at least 12 months; in this case, following the veterinary checks provided for in Directive 97/78/EC, and in accordance with the conditions laid down in Article 8(4) of that Directive, the products must be transported directly to the registered establishment or plant of destination and all precautions, including safe disposal of waste, unused or surplus material, must be taken to avoid risks of spreading diseases to animals or humans.
- 3.2. In addition to point (b)(i) and (ii) of point 3.1, in the case of animals other than Suidae and Tayassuidae, one of the following conditions must be complied with:
  - (a) in the third country or region of origin no case of vesicular stomatitis and bluetongue (including the presence of seropositive animals) has been recorded for a period of at least 12 months and vaccination has not been carried out against those diseases for a period of at least 12 months in the susceptible species;
  - (b) following the veterinary checks provided for in Directive 97/78/EC, and in accordance with the conditions laid down in Article 8(4) of that Directive, the products must be transported directly to the plant of destination and all precautions, including safe disposal of waste, unused or surplus material, must be taken to avoid risks of spreading diseases to animals or humans.
- 3.3. In addition to point (b)(i) and (ii) of point 3.1, in the case of Suidae and Tayassuidae, in the third country or region of origin no case of swine vesicular disease, classical swine

(b)

fever and African swine fever has been recorded for a period of at least 12 months, vaccination has not been carried out against those diseases for a period of at least 12 months and one of the following conditions are complied with:

- (a) in the country or region of origin no case of vesicular stomatitis (including the presence of seropositive animals) has been recorded for a period of 12 months and vaccination has not been carried out against this disease for a period of at least 12 months in the susceptible species;
- (b) following the veterinary checks provided for in Directive 97/78/EC, and in accordance with the conditions laid down in Article 8(4) of that Directive, the products must be transported directly to the registered establishment or plant of destination and all precautions, including safe disposal of waste, unused or surplus material, must be taken to avoid risks of spreading diseases to animals or humans.
- 4. In the case of blood products for the manufacture of derived products for uses outside the feed chain for farmed animals which have been derived from poultry and other avian species, they must comply with the following conditions of either point (a) or (b):
  - (a) the products must have undergone one of the following treatments guaranteeing the absence of pathogens of the diseases referred to in point (b):
    - (i) heat treatment at a temperature of 65 °C for at least three hours, followed by an effectiveness check;
    - (ii) irradiation at 25 kGy by gamma rays, followed by an effectiveness check;
    - (iii) heat treatment of at least 70 °C throughout their substance, followed by an effectiveness check;
  - (b) in case of blood products not treated in accordance with point (a) the products must originate from a third country or region:
    - (i) which has been free from Newcastle disease and highly pathogenic avian influenza as listed in the Terrestrial Animal Health Code of the OIE, 2010 edition;
    - (ii) which during the last 12 months has not carried out vaccination against avian influenza;
    - (iii) where the poultry or other avian species from which the products derive have not been vaccinated against Newcastle disease with vaccines prepared from a Newcastle disease master strain showing a higher pathogenicity than lentogenic virus strains.

## Section 3

## Imports of blood and blood products from equidae

The following requirements shall apply to the import of blood and blood products from equidae:

1. [<sup>F1</sup>The blood must comply with the conditions set out in point 1(a) of Chapter IV of Annex XIII and must be collected under veterinary supervision:

- (a) in slaughterhouses:
  - (i) approved in accordance with Regulation (EC) No 853/2004; or
  - (ii) approved and supervised by the competent authority of the country of collection; or
- (b) from live equidae in facilities approved and furnished with a veterinary approval number and supervised by the competent authority of the country of collection for the purpose of collecting blood from equidae for the production of blood products for purposes other than feeding.]
- 2. The blood products must comply with the conditions set out in point 2 of Chapter IV of Annex XIII.

In addition, the blood products referred to in point 2(b)(i) of Chapter IV of Annex XIII must be produced from blood collected from equidae which have been kept for a period of at least three months, or since birth if less than three months old, prior to the date of collection on holdings under veterinary supervision in the third country of collection which during that period and the period of blood collection has been free of:

- (a) African horse sickness in accordance with points (a) and (b) of the first subparagraph of Article 5(2) of Directive 2009/156/EC;
- (b) Venezuelan equine encephalomyelitis for a period of at least two years;
- (c) glanders:
  - (i) for a period of three years; or
  - (ii) for a period of six months where the animals have shown no clinical signs of glanders (*Burkholderia mallei*) during the post-mortem inspection in the slaughterhouse referred to in point 1(a), including a careful examination of mucous membranes from the trachea, larynx, nasal cavities and sinuses and their ramifications, after splitting the head in the median plane and excising the nasal septum;
- (d) [<sup>F1</sup>in the case of blood products other than serum and plasma, vesicular stomatitis for a period of at least six months.]
- 3. Blood products must come from an establishment or plant which has been approved or registered by the competent authority of the third country.
- 4. Blood and blood products shall be packed and labelled in accordance with point 3 of Chapter IV of Annex XIII.

#### Section 4

#### Imports of hides and skins of ungulates

The following requirements shall apply to the import of hides and skins of ungulates:

1. Fresh or chilled hides and skins may be imported if:

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- (a) they come from a third country referred to in the applicable column of row 4 of Table 2 set out in Section 1 which, as appropriate to the species concerned:
  - (i) for a period of at least 12 months before dispatch, has been free from all of the following diseases:
    - classical swine fever,
    - African swine fever, and
    - Rinderpest; and
  - (ii) has been free from foot-and-mouth disease for a period of at least 12 months before the date of dispatch and where, for a period of at least 12 months before the date of dispatch, no vaccination has been carried out against that disease;
- (b) they have been obtained from:
  - (i) animals that have remained in the territory of the third country of origin for a period of at least three months before being slaughtered or since birth in the case of animals less that three months old;
  - (ii) in the case of hides and skins from bi-ungulates, animals that come from holdings in which there has been no outbreak of foot-and mouth disease in the previous 30 days, and around which within a radius of 10 km there has been no case of foot-and-mouth disease for 30 days;
  - (iii) in the case of hides and skins from swine, animals that come from holdings in which there has been no outbreak of swine vesicular disease in the previous 30 days, or of classical or African swine fever in the previous 40 days, and around which within a radius of 10 km there has been no case of these diseases for 30 days; or
  - (iv) animals that have passed the ante-mortem health inspection at the slaughterhouse during the 24 hours before slaughter and have shown no evidence of foot-and-mouth disease, rinderpest, classical swine fever, African swine fever or swine vesicular disease; and
- (c) they have undergone all precautions to avoid recontamination with pathogenic agents.
- 2. Treated hides and skins referred to in point C.2 of Chapter V of Annex XIII may be imported without any restrictions.
- 3. Other treated hides and skins may be imported if:
  - (a) they come either from:
    - a third country or, in the case of regionalisation in accordance with Union legislation, from a part of a third country, appearing on the list set out in point (a) of the column 'third countries' list' of row 5 of Table 2 set out in Section 1 from which imports of fresh meat of the corresponding species are authorised and they have been treated as referred to in point 28(a), (b) and (c) of Annex I;

- (ii) a third country appearing on the list set out in point (a) of the applicable column of row 5 of Table 2 set out in Section 1 and they have been treated as referred to in point 28(c) or (d) of Annex I; or
- (iii) equidae or ruminant animals from a third country appearing on the list set out in point (b) of the column 'third countries' list' of row 5 of Table 2 of Section 1, and have been treated as referred to in point 28(a), (b) and (c) of Annex I and after treatment have been kept separate for a period of at least 21 days; and
- (b) in the case of salted hides and skins transported by ship, they have been treated as referred to in point 28(b) or (c) of Annex I and have been kept separated after treatment during transportation for a period of at least 14 days in the case of the treatment referred to in point 28(b) or seven days in the case of the treatment referred to in point 28(c) before importation and the health certificate accompanying the consignment attests such treatment and the duration of the transportation.
- 4. Fresh, chilled or treated hides and skins of ungulates must be imported in containers, road vehicles, railway wagons or bales sealed under the responsibility of the competent authority of the third country of dispatch.

## Section 5

## Imports of game trophies and other preparations from animals

The following requirements shall apply to the import of game trophies and other preparations from animals:

- 1. Game trophies or other preparations from animals which fulfil the conditions referred to in points B and C.1 of Chapter VI of Annex XIII may be imported without restrictions.
- 2. Treated game trophies or other preparations from birds and ungulates, being solely comprised of bones, horns, hooves, claws, antlers, teeth, hides or skins, from third countries may be imported if they comply with the requirements of point C.1(a) and point C.2(a), (i) to (iii) and (b)(i) and (ii) of Chapter VI of Annex XIII.

However, in the case of dry-salted or wet-salted skins transported by ship, the skins need not be salted 14 days before dispatch, provided that they are salted for 14 days before importation.

- 3. Game trophies or other preparations from birds and ungulates consisting of entire anatomical parts, not having been treated in any way may be imported if:
  - (a) they come from animals originating in an area not subject to restrictions as a result of the presence of serious transmissible diseases to which animals of the species concerned are susceptible;
  - (b) they were packaged without being in contact with other products of animal origin likely to contaminate them, in individual, transparent and closed packages so as to avoid any subsequent contamination.

#### Section 6

#### Imports of treated feathers, parts of feathers and down

Treated feathers and parts of feathers and down may be imported:

- (a) if they are treated decorative feathers, treated feathers carried by travellers for their private use or consignments of treated feathers or down sent to private individuals for non-industrial purposes; or
- (b) if they are accompanied by a commercial document stating that the feathers and parts of feathers or down have been treated with a steam current or by another method that ensures that no unacceptable risks remain and are securely enclosed in packaging and dry; and
- (c) unless the commercial document states that they have been factory-washed and treated with hot steam at 100 °C for at least 30 minutes, they are sent to a registered establishment or plant for such treatment.

#### Section 7

#### Imports of bones and bone products (excluding bone meal), horns and horn products (excluding horn meal) and hooves and hoof products (excluding hoof meal) intended for use other than as feed material, organic fertilisers or soil improvers

- 1. Bones and bone products (excluding bone meal), horns and horn products (excluding horn meal) and hooves and hoof products (excluding hoof meal) may be imported to produce derived products for uses outside the feed chain if:
- (a) the products are dried before export to the Union and not chilled or frozen;
- (b) [<sup>F3</sup>the products are conveyed from the third country of origin directly to a border inspection post of entry into the Union and are not transhipped at any port or place outside the Union;]
- (c) following the document checks provided for in Directive 97/78/EC, the products are conveyed directly to the registered establishment or plant of destination.
- 2. Each consignment must be accompanied by a commercial document stamped by the competent authority supervising the establishment of origin, including the following information:
- (a) the third country of origin;
- (b) the name of the establishment or plant of production;
- (c) the nature of the product (dried bone/dried bone product/dried horns/dried horn products/dried hooves/dried hoof products), and
- (d) confirmation of the fact that the product was:
  - (i) derived from healthy animals slaughtered in a slaughterhouse;
  - (ii) dried for a period of 42 days at an average temperature of at least 20 °C;
  - (iii) heated for one hour to at least 80 °C to the core before drying;

- (iv) ashed for one hour to at least 800 °C to the core before drying;
- (v) underwent an acidification process such that the pH was maintained at less than 6 to the core for at least one hour before drying, and

is not intended at any stage to be diverted for any use in food, feed material, organic fertilisers or soil improvers.

3. On dispatch to the Union, the material must be enclosed in sealed containers or vehicles or carried in bulk in a ship.

If transported in containers, the containers, and in all cases all the accompanying documents, must bear the name and the address of the registered establishment or plant of destination.

4. Following the veterinary checks provided for in Directive 97/78/EC, and in accordance with the conditions laid down in Article 8(4) of that Directive, the material must be transported directly to the registered establishment or plant of destination.

#### Section 8

#### Imports of animal by-products for the manufacture of feed for fur animals, petfood, other than raw petfood, and derived products for uses outside the feed chain for farmed animals

Animal by-products intended for the manufacture of feed for fur animals, petfood, other than raw petfood, and for derived products for uses outside the feed chain for farmed animals may be imported provided that:

- 1. the animal by-products have been deep-frozen at the plant of origin or have been preserved in accordance with Union legislation in such a way to prevent spoiling between dispatch and delivery to the establishment or plant of destination;
- 2. the animal by-products have undergone all precautions to avoid contamination with pathogenic agents;
- 3. the animal by-products were packed in new packaging preventing any leakage or in packaging which has been cleaned and disinfected before use;
- 4. following the veterinary checks provided for in Directive 97/78/EC, and in accordance with the conditions laid down in Article 8(4) of that Directive, the animal by-products are transported directly either to:
  - (a) a petfood plant or to a registered establishment or plant of destination, which has provided a guarantee that the animal by-products shall be used only for the purpose of producing the products for which it has been registered or approved, as applicable, as specified by the competent authority if necessary, and shall not leave the establishment or plant untreated other than for direct disposal;
  - (b) an establishment or plant which has been approved in accordance with Article 24(1)(h) of Regulation (EC) No 1069/2009;
  - (c) a registered user or collection centre, which has provided a guarantee that the animal by-products shall be used only for permitted purposes, as specified by the competent authority if necessary; or

- (d) an establishment or plant which has been approved in accordance with Article 24(1)(a) of Regulation (EC) No 1069/2009; and
- 5.1. in the case of raw material for petfood production referred to in Article 35(a)(ii) of Regulation (EC) No 1069/2009, the raw material shall:
  - (a) be marked in the third country before entry into the Union by a cross of liquefied charcoal or activated carbon, on each outer side of each frozen block, or, when the raw material is transported in pallets which are not divided into separate consignments during transport to the petfood plant of destination, on each outer side of each pallet, in such a way that the marking covers at least 70 % of the diagonal length of the side of the frozen block and is at least 10 cm in width;
  - (b) in the case of material which is not frozen, be marked in the third country before entry into the Union by spraying it with liquefied charcoal or by applying charcoal powder in such a way that the charcoal is clearly visible on the material;
  - (c) be transported directly to:
    - (i) the petfood plant of destination in accordance with point 4(a); or
    - (ii) an establishment or plant of destination which has been approved in accordance with Article 24(1)(h) of Regulation (EC) No 1069/2009, in accordance with point 4(b) of this Section and from there directly to the petfood plant referred to under (i), provided that the plant of destination:
      - only handles material covered by this point 5.1, or
      - only handles material destined for a petfood plant as referred to under (i); and
  - (d) be manipulated to remove the marking provided for in points (a) and (b) only in the petfood plant of destination and only immediately prior to use of the material for the manufacture of petfood, in accordance with the conditions applicable to petfood produced from Category 3 material set out in Chapter II of Annex XIII;
- 5.2. in the case of consignments made up of raw material, which has been treated as referred to in point 5.1 above and other non-treated raw material, all the raw materials in the consignment have been marked as laid down in point 5.1(a) and (b) above;
- 5.3. the marking referred to in point 5.1(a) and (b) and point 5.2 remains visible from the dispatch and until the delivery to the petfood plant of destination;
- 6. In the petfood plant of destination, raw material for petfood production referred to in Article 35(a)(ii) of Regulation (EC) No 1069/2009 shall be stored before production, used and disposed of under conditions authorised by the competent authority, which allow official controls on the amounts of material received, used for production and disposed of, if applicable.

The competent authority may authorise the operator of the petfood plant to store such materials together with Category 3 material.

#### Section 9

#### Imports of rendered fats for certain purposes outside the feed chain for farmed animals

Rendered fats which are not destined to the production of feed for farmed animals, the manufacture of cosmetics, medicinal products or medical devices, may be imported, provided:

- (a) they are derived from:
  - (i) [<sup>F1</sup>in the case of materials destined for the production of biodiesel or oleochemical products, animal by-products referred to in Articles 8, 9 and 10 of Regulation (EC) No 1069/2009;]
  - (ii) in the case of materials destined to the production of organic fertilisers and soil improvers, Category 2 materials referred to in points (c), (d) and (f)(i) of Article 9 of Regulation (EC) No 1069/2009, or Category 3 materials, other than materials referred to in points (c) and (p) of Article 10 of Regulation (EC) No 1069/2009;
  - (iii) [<sup>F5</sup>in the case of materials destined to the production of renewable fuels referred to in point J of Section 2 of Chapter IV of Annex IV of this Regulation, Category 2 materials referred to in Article 9 of Regulation (EC) No 1069/2009 and Category 3 materials referred to in Article 10 of that Regulation;
  - (iv) in the case of other materials Category 1 materials referred to in points (b), (c) and (d) of Article 8 of Regulation (EC) No 1069/2009, Category 2 materials referred to in points (c) and (d) and point (f)(i) of Article 9 of Regulation (EC) No 1069/2009 or Category 3 materials, other than the materials referred to in points (c) and (p) of Article 10 of that Regulation;]
- (b) they have been processed by processing method 1 (pressure sterilisation) or in accordance with one of the other processing methods referred to in Chapter III of Annex IV;
- (c) in the case of fat from ruminant origin, insoluble impurities in excess of 0,15 % by weight have been removed;
- (d) they have been marked before shipment to the Union so that the minimum concentration of GTH referred to in point 1(b) of Chapter V of Annex VIII is achieved;
- (e) following the veterinary checks provided for in Directive 97/78/EC, and in accordance with the conditions laid down in Article 8(4) of that Directive, the rendered fats are transported directly to the registered establishment or plant of destination, under conditions which prevent contamination; and
- (f) they bear labels, on the packaging or container indicating 'NOT FOR HUMAN OR ANIMAL CONSUMPTION'.

#### Section 10

#### **Imports of fat derivatives**

1. Fat derivatives may be imported if the health certificate accompanying the consignment certifies:

- (a) whether the fat derivatives derive from Category 1, 2 or 3 materials;
- (b) in the case of fat derivatives produced from Category 2 material, that the products:
  - (i) have been produced using a method that at least meets the standards of one of the processes referred to in point 1 of Chapter XI of Annex XIII; and
  - (ii) shall only be used in organic fertiliser or soil improvers or other uses outside the feed chain for farmed animals, other than in cosmetics, pharmaceuticals and medical devices;
- (c) in the case of fat derivatives produced from Category 1 material, that the products must not be used in organic fertilisers and soil improvers, cosmetics, pharmaceuticals and medical devices; however, they may be used for other purposes outside the feed chain for farmed animals.
- 2. The health certificate referred to in point 1 must be presented to the competent authority at the border inspection post at the first point of entry of the goods into the Union, and thereafter a copy must accompany the consignment until its arrival at the plant of destination.
- 3. Following the veterinary checks provided for in Directive 97/78/EC, and in accordance with the conditions laid down in Article 8(4) of that Directive, the fat derivatives shall be transported directly to the registered establishment or plant of destination.

## Section 11

#### **Imports of photogelatine**

- 1. Gelatine which has been produced from material containing bovine vertebral column comprising of Category 1 material in accordance with Article 8(b) of Regulation (EC) No 1069/2009 and which is intended for the photographic industry (photogelatine) may be imported, provided the photogelatine:
- (a) originates from one of the plants of origin indicated in Table 3;
- (b) has been produced in accordance with point 6;
- (c) is imported through one of the border inspection posts of first entry into the Union indicated in Table 3; and
- (d) is destined for production in an approved photographic factory indicated in Table 3.

## TABLE 3

Third country of origin	Plants of origin	Member State of destination	Border inspection post of first entry into the Union	Approved photographic factories
Japan	Nitta Gelatin Inc., 2-22 Futamata Yao-City, Osaka	The Netherlands	Rotterdam	FujifilmEurope, Oudenstaart 1, 5047 TK Tilburg,

## **Imports of photogelatine**

	581-0024 Japan Jellie Co. Ltd. 7-1, Wakabayashi 2- Chome, Wakabayashi-ku, Sendai-City; Miyagi, 982 Japan NIPPI Inc. Gelatine Division 1 Yumizawa- Cho Fujinomiya City Shizuoka 418-0073 Japan			The Netherlands
	Nitta Gelatin Inc., 2-22 Futamata Yao-City, Osaka 581-0024 Japan	United Kingdom	Liverpool Felixstowe Heathrow	Kodak Ltd. Headstone Drive, Harrow, Middlesex, HA4 4TY, United Kingdom
		Czech Republic	Hamburg	FOMA Bohemia, spol. SRO Jana Krušinky 1604 501 04 Hradec Králove, Czech Republic
United States	Eastman Gelatine Corporation, 227 Washington Street, Peabody, MA, 01960 USA	United Kingdom	Liverpool Felixstowe Heathrow	Kodak Ltd. Headstone Drive, Harrow, Middlesex, HA4 4TY, United Kingdom
	Gelita North America, 2445 Port Neal Industrial Road Sergeant Bluff, Iowa, 51054 USA	Czech Republic	Hamburg	FOMA Bohemia spol. SRO Jana Krušinky 1604 501 04 Hradec Králove, Czech Republic

2. Once the photogelatine has entered the Member State of destination, it shall not be traded between Member States but shall only be used in the approved photographic

factory in the same Member State of destination and solely for photographic production purposes.

- 3. Following the veterinary checks provided for in Directive 97/78/EC, and in accordance with the conditions laid down in Article 8(4) of that Directive, the photogelatine shall be transported directly to the approved photographic factory of destination.
- 4. The transport referred to in point 3 shall be carried out in vehicles or containers in which the photogelatine is physically separated from any products intended for food or feed.
- 5. In the approved photographic factory of destination, the operator shall ensure that any surpluses or residues of and other waste derived from the photogelatine are:
- (a) transported in sealed leak-proof containers labelled 'for disposal only' in vehicles under satisfactory hygiene conditions;
- (b) disposed of in accordance with Article 12(a)(i) of Regulation (EC) No 1069/2009 or exported to the third country of origin in accordance with Regulation (EC) No 1013/2006.
- 6. Photogelatine shall be produced according to the following requirements:
- (a) Photogelatine shall only be produced in plants which do not produce gelatine for food or feed intended for dispatch to the European Union, and which are approved by the competent authority of the third country concerned.
- (b) Photogelatine shall be produced by a process that ensures that raw material is treated by processing method 1 (pressure sterilisation) as referred to in Chapter III of Annex IV or subjected to a treatment with acid or alkali for a period of at least two days, washing with water, and:
  - (i) following an acid treatment, treating with alkaline solution for a period of at least 20 days; or
  - (ii) following an acid treatment, treating with an acid solution for a period of 10 to 12 hours.

The pH must then be adjusted and the material purified by means of filtration and sterilisation at 138 °C to 140 °C for 4 seconds.

- (c) After having been subjected to the process referred to in point (b), the photogelatine may undergo a drying process and, where appropriate, a process of pulverisation or lamination.
- (d) The photogelatine shall be wrapped, packaged in new packages, stored and transported in sealed leak-proof, labelled containers in a vehicle under satisfactory hygiene conditions.

If leakage is observed, the vehicle and containers shall be thoroughly cleaned and inspected before reuse.

(e) Wrapping and packages containing the photogelatine must carry the words 'photogelatine for the photographic industry only'.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011. (See end of Document for details)

#### Section 12

#### Imports of horns and horn products, excluding horn meal, and hooves and hoof products, excluding hoof meal, intended for the production of organic fertilisers or soil improvers

Horns and horn products, excluding horn meal, and hooves and hoof products, excluding hoof meal, intended for the production of organic fertilizers or soil improvers, may be imported, provided that:

- 1. they have been produced in accordance with Chapter XII of Annex XIII; and
- 2. they are conveyed following the veterinary checks provided for in Directive 97/78/ EC, and in accordance with the conditions laid down in Article 8(4) of that Directive, directly to an approved or registered establishment or plant.

## CHAPTER III

## SPECIAL RULES FOR CERTAIN SAMPLES

## Section 1

## **Research and diagnostic samples**

Unless they are kept for reference purposes or redispatched to the third country of origin, research and diagnostic samples and any products derived from the use of those samples shall be disposed of:

- (a) as waste by incineration;
- (b) by pressure sterilisation and subsequent disposal or use in accordance with Articles 12 to 14 of Regulation (EC) No 1069/2009; or
- (c) in accordance with point 4(b) of Section 1 of Chapter I of Annex VI in case:
  - (i) of quantities not exceeding 2 000 ml; and
  - (ii) provided the samples or derived products have been produced in and dispatched from third countries or parts of third countries, from which Member States authorise imports of fresh meat of domestic bovine animals, which are listed in Part I of Annex II to Regulation (EU) No 206/2010.

## Section 2

#### **Trade samples**

- 1. The competent authority may authorise the import and transit of trade samples, provided that:
- (a) they originate from:
  - (i) third countries referred to in the column 'third countries' list' of row 14 of Table 2 of Section 1 of Chapter II of this Annex;

- (ii) in the case of trade samples which consist of milk, milk-based products or milk-derived products, authorised third countries listed in Annex I to Regulation (EU) No 605/2010;
- (b) they are accompanied by a health certificate as referred to in Chapter 8 of Annex XV; and
- (c) following the veterinary checks provided for in Directive 97/78/EC, and in accordance with the conditions laid down in Article 8(4) of that Directive, they are transported directly to the approved or registered establishment or plant indicated in the authorisation of competent authority.
- 2. Unless the trade samples are kept for reference purposes, they shall be:
- (a) disposed of or used in accordance with Articles 12, 13 and 14 of Regulation (EC) No 1069/2009; or
- (b) redispatched to the third country of origin.
- 3. If trade samples are used for testing of machinery, the testing shall be carried out:
- (a) with dedicated equipment; or
- (b) with equipment which is cleaned and disinfected before it is used for purposes other than the testing.

During transport to the approved or registered establishment or plant, the trade samples must be packaged in leak-proof containers.

#### Section 3

#### **Display items**

- 1. Import and transit of display items shall take place in accordance with the following conditions:
- (a) they originate from third countries referred to in the column 'third countries' list' of row 14 of Table 2 of Section 1 of Chapter II;
- (b) their introduction has been authorised in advance by the competent authority of the Member State where the display item is intended to be used;
- (c) following the veterinary checks provided for in Directive 97/78/EC, display items must be sent directly to the authorised user.
- 2. Each consignment must be packed in packaging preventing any leakage and must be accompanied by a commercial document which specifies:
- (a) the description of the material and the animal species of origin;
- (b) the category of the material;
- (c) the quantity of the material;
- (d) the place of dispatch of the material;
- (e) the name and the address of the consignor;

- (f) the name and the address of the consignee; and
- (g) details allowing the identification of the authorisation of the competent authority of destination.
- 3. After the exhibition or after the artistic activity has been concluded, display items shall be:
- (a) redispatched to the third country of origin;
- (b) dispatched to another Member State or third country, if such dispatch has been authorised by the competent authority of the Member State or third country of destination in advance; or
- (c) disposed of in accordance with Articles 12, 13 and 14 of Regulation (EC) No 1069/2009.

## CHAPTER IV

## SPECIFIC REQUIREMENTS FOR CERTAIN MOVEMENTS OF ANIMAL BY-PRODUCTS

#### Section 1

#### **Imports of certain Category 1 materials**

Materials referred to in Article 26 shall be imported under the following conditions:

- 1. The materials shall be imported with a label attached to the packaging, container or vehicle which indicates 'Prohibited in food, feed, fertilisers, cosmetics, medicinal products and medical devices'.
- 2. The materials shall be directly delivered to an approved or registered establishment or plant for the manufacture of derived products, other than the products referred to in point 1.
- 3. Unused or surplus materials shall be used or disposed of in accordance with Article 12 of Regulation (EC) No 1069/2009.

#### Section 2

#### Imports of certain materials for purposes other than feeding to farmed land animals

- 1. The competent authority may authorise the import of the following materials for purposes other than feeding to farmed land animals, except for feeding to fur animals, provided there is no unacceptable risk for the transmission of diseases communicable to humans or animals:
- (a) animal by-products from aquatic animals and derived products from aquatic animals;
- (b) aquatic invertebrates and derived products from aquatic invertebrates;
- (c) terrestrial invertebrates, including any of their transformation forms, such as larvae, and derived products therefrom;

- (d) products generated by the animals referred to in points (a), (b) and (c), such as fish eggs;
- (e) Category 3 material comprising of animals and parts thereof of the zoological orders of Rodentia and Lagomorpha.
- 2. Imports of consignments of the materials referred to in point 1 shall take place in accordance with sanitary certification requirements in accordance with national rules.

#### ANNEX XV

#### **MODEL HEALTH CERTIFICATES**

The model health certificates in this Annex shall apply to the importation from third countries and to the transit through the European Union of the animal by-products and the derived products referred to in the respective model health certificates. *Notes* 

- (a) Veterinary certificates shall be produced by the exporting third country, based on the models set out in this Annex, according to the layout of the model that corresponds to the animal by-products or derived products concerned. They shall contain, in the numbered order that appears in the model, the attestations that are required for any third country and, as the case may be, those supplementary guarantees that are required for the exporting third country or part thereof.
- (b) Where the model certificate states that certain statements shall be kept as appropriate, statements which are not relevant may be crossed out and initialled and stamped by the certifying officer, or completely deleted from the certificate.
- (c) The original of each certificate shall consist of a single sheet of paper, both sides, or, where more text is required; it shall be in such a form that all sheets of paper needed are part of an integrated whole and indivisible.
- (d) It shall be drawn up in at least one of the official languages of the EU Member State in which the inspection at the border post shall be carried out and of the EU Member State of destination. However, these Member States may allow other languages, accompanied, if necessary, by an official translation.
- (e) If for reasons of identification of the items of the consignment, additional sheets of paper are attached to the certificate, these sheets of paper shall also be considered as forming part of the original of the certificate by the application of the signature and stamp of the certifying official veterinarian, in each of the sheets of paper.
- (f) When the certificate, including additional schedules referred to in e), comprises more than one page, each page shall be numbered (*page number*) of (*total number of pages*) at the bottom of the page and shall bear the code number of the certificate that has been designated by the competent authority at the top of the page.
- (g) The original of the certificate must be completed and signed by an official veterinarian. In doing so, the competent authorities of the exporting country shall ensure that the principles of certification equivalent to those laid down in Directive 96/93/EC are followed.

- (h) The colour of the signature shall be different to that of the printing. The same rule applies to stamps other than those embossed or watermark.
- (i) The original of the certificate must accompany the consignment at the EU border inspection post.
- (j) If health certificates are used for consignments in transit, box No I.5 ('Consignee') of the relevant health certificate shall be completed with the name and address of the border inspection post through which the consignment is intended to leave the European Union.

## CHAPTER 1

#### Health certificate

For processed animal protein not intended for human consumption, including mixtures and products other than petfood containing such protein, for dispatch to or for transit through  $\binom{2}{}$  the European Union

cou	NTRY	,	Veterinary certificate to EU
	l.1.	Consignor	I.2. Certificate reference No I.2.a.
		Name	I.3. Central competent authority
		Address	I.3. Central competent authority
		Tel.	I.4. Local competent authority
t	1.5.	Consignee	I.6. Person responsible for the load in EU
me		Name	Name
sigr		Address	Address
Co		Postcode	Postcode
bec		Tel.	Tel.
atcl		T	
disp	1.7.	Country of origin ISO code I.8. Region of origin Code	I.9. Country of ISO code I.10. Region of Code
õ			destination destination
Part I: Details of dispatched consignment	1 1 1	Place of origin	I.12. Place of destination
De			1.12. Place of destination
Ţ		Name Approval number	Name Custom warehouse
۳ ۳		Address	Address Approval number
		Name Approval number Address	Postcode
		Name Approval number	Posicode
	1.13	Address Place of loading	I.14. Date of departure
		have of fouring	
	1.15.	Means of transport	I.16. Entry BIP in EU
		Aeroplane 🗌 Ship 🗌 Railway wagon 🗌	
		Road vehicle Other	1.17.
		Identification	
		Documentation references	
	I.18.	Description of commodity	I.19. Commodity code (HS code)
			I.20. Quantity
	121	Temperature of product	I.22. Number of packages
		Ambient Chilled	Frozen
	1.23.	Seal/Container No	I.24. Type of packaging
	1.25.	Commodities certified for:	
		Animal feedingstuff Technical use	
	1.26.	For transit through EU to third country	I.27. For import or admission into EU
		Third country ISO code	
	1.28.	Identification of the commodities	
	(		umber of establishments Net weight Batch number nufacturing plant

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011. (See end of Document for details)

со	Processed animal protein not intended for human consumption including mixtures and UNTRY other than petfood containing such protein										
	П.	Health information	II.a. Certificate reference No	II.b.							
		I, the undersigned official veterinarian, declare that I have read and of the Council ( $^{1a}$ ) and in particular Article 10 thereof, and Chapter II, Section 1, and Annex XIV, Chapter I, thereof and c	Commission Regulation (EU) No 142/2								
ation	II.1.	the processed animal protein or product described above consumption that:	contains exclusively processed anima	I protein not intended for human							
Part II: Certification		(a) has been prepared and stored in an establishment or plant approved, validated and supervised by the competent au accordance with Article 24 of Regulation (EC) No 1069/2009, and									
art		(b) has been prepared exclusively with the following animal by	(b) has been prepared exclusively with the following animal by-products:								
		( <sup>2</sup> ) either [- carcases and parts of animals slaughtered or human consumption in accordance with Unio reasons;]									
		( <sup>2</sup> ) and/or [- carcases and the following parts originating were considered fit for slaughter for human or parts of animals from game killed for human	onsumption following an ante-mortem ins	spection or bodies and the following							
		<ul> <li>(i) carcases or bodies and parts of animal Union legislation, but which did not show</li> </ul>									
		(ii) heads of poultry;									
		<ul><li>(iii) hides and skins, including trimmings and and metacarpus bones, tarsus and meta</li></ul>									
		(iv) pig bristles;									
		(v) feathers;]									
		( <sup>2</sup> ) and/or [- blood of animals which did not show any sig from animals other than ruminants that have slaughter for human consumption following a	been slaughtered in a slaughterhouse	after having been considered fit for							
		( <sup>2</sup> ) and/or [- animal by-products arising from the production greaves and centrifuge or separator sludge		umption, including degreased bone,							
		( <sup>2</sup> ) and/or [- products of animal origin, or foodstuffs cont consumption for commercial reasons or due which no risk to public or animal health aris	to problems of manufacturing or packa								
		( <sup>2</sup> ) and/or [- blood, placenta, wool, feathers, hair, horns, h of any disease communicable through that p		ive animals that did not show signs							
		( <sup>2</sup> ) and/or [- aquatic animals, and parts of such animals, except sea mammals, which did not show any signs of diseases nicable to humans or animals;]									
		( <sup>2</sup> ) and/or [- animal by-products from aquatic animals originating from establishments or plants manufacturing products fo consumption;]									
		( <sup>2</sup> ) and/or [- the following material originating from animals which did not show any signs of disease communicable through material to humans or animals:									
		(i) shells from shellfish with soft tissue or flesh;									
		(ii) the following originating from terrestrial a	animals:								
		<ul> <li>hatchery by-products,</li> <li>eggs,</li> </ul>									
		<ul> <li>egg by-products, including egg shells</li> </ul>	8;								
		(iii) day-old chicks killed for commercial reas	sons;]								

COUNT	RY	Processed animal protein not other than petfood containing s	intended for human consumption is such protein	ncluding mixtures and products		
П.	Health inform	ation	II.a. Certificate reference No	II.b.		
	( <sup>2</sup> ) and/or [- aquatic and terrestrial invertebrates other than species pathogenic to humans or animals;]					
	( <sup>2</sup> ) and/or [- animals and parts thereof of the zoological orders of Rodentia and Lagomorpha, except Category 1 material a to in Article 8(a)(iii), (iv) and (v) and Category 2 material as referred to in Article 9(a) to (g) of Regula No 1069/2009;]					
	and					
	(c) has been s	subjected to the following processing standard:				
	( <sup>2</sup> ) either	[heating to a core temperature of more than 133 least 3 bars produced by saturated steam, wi				
	( <sup>2</sup> ) or	[in the case of non-mammalian protein other tha out in Annex IV, Chapter III, of Regulation (EU)		2-3-4-5-7 as set		
	( <sup>2</sup> ) or	[in the case of fishmeal the processing method Regulation (EU) No 142/2011;]	1-2-3-4-5-6-7 as s	et out in Annex IV, Chapter III, of		
	( <sup>2</sup> ) or	[in the case of porcine blood, the processing m Regulation (EU) No 142/2011, where in case of its substance;]				
II.2.	the competent	authority examined a random sample immediatel	y prior to dispatch and found it to com	ply with the following standards (3):		
	Salmonella:	Absence in 25 g: $n = 5$ , $c = 0$ , $m = 0$	, M = 0			
	Enterobacteria	ceae: n = 5, c = 2, m = 10, M = 300 in 1 g	;			
11.3.	the end produ-	ct:				
	(2) either	[was packed in new or sterilised bags,]				
	( <sup>2</sup> ) or	[was transported in bulk in containers or other me	eans of transport that were thoroughly o	leaned and disinfected before use,]		
	which bear lab	els indicating 'NOT FOR HUMAN CONSUMPTIC	DN';			
II.4.	the end produ-	ct was stored in enclosed storage;				
II.5.	the product ha	is undergone all precautions to avoid recontamina	ation with pathogenic agents after trea	tment;		
II.6.						
	( <sup>2</sup> ) either	[the product does not contain and is not derived 999/2001 of the European Parliament and of bovine, ovine or caprine animals; and the anim stunning by means of gas injected into the cra central nervous tissue by means of an elongate	the Council ( <sup>4</sup> ) or mechanically separa nals from which this product is derive nial cavity or killed by the same meth	ated meat obtained from bones of d have not been slaughtered after nod or slaughtered by laceration of		
	(²) or	[the product does not contain and is not derive animals born, continuously reared and slaughter decision in accordance with Article 5(2) of Regu	red in a country or region classified as			
Notes						
Part I:						
		Person responsible for the consignment in the Eu be filled in if the certificate is for import commodi		n only if it is a certificate for transit		
		Place of destination: this box is to be filled in only ones, free warehouses and custom warehouses.	y if it is a certificate for transit commod	ity. The products in transit can only		
		Registration number (railway wagons or containent of unloading and reloading.	er and lorries), flight number (aircraft) o	or name (ship); information is to be		
- Box	reference I.19:	use the appropriate HS code: 05.05; 05.06; 05.0	07 or 23.01.			
- Box	reference I.25:	technical use: any use other than for animal con	sumption.			
— Box	reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.					

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011. (See end of Document for details)

II.       Health information       II.a. Certificate reference No       II.b.         Part II:       (1a) OJ L 300, 14.11.2009, p. 1.       (1b) OJ L 54, 26.2.2011, p. 1.       (1b) OJ L 54, 26.2.2011, p. 1.         ( <sup>1b</sup> ) OJ L 54, 26.2.2011, p. 1.       ( <sup>2</sup> ) Delete as appropriate.       ( <sup>3</sup> ) Where:       ( <sup>3</sup> ) Where:         n = number of samples to be tested;       m = threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria in all samples does not m;         M       maximum value for the number of bacteria; the result is considered unsatisfactory if the number of bacteria in all samples does not m;							
<ul> <li>(<sup>1a</sup>) OJ L 300, 14.11.2009, p. 1.</li> <li>(<sup>1b</sup>) OJ L 54, 26.2.2011, p. 1.</li> <li>(<sup>2</sup>) Delete as appropriate.</li> <li>(<sup>3</sup>) Where: <ul> <li>n = number of samples to be tested;</li> <li>m = threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria in all samples does not m;</li> </ul> </li> </ul>							
<ul> <li>(<sup>1b</sup>) OJ L 54, 26.2.2011, p. 1.</li> <li>(<sup>2</sup>) Delete as appropriate.</li> <li>(<sup>3</sup>) Where: <ul> <li>n = number of samples to be tested;</li> <li>m = threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria in all samples does not m;</li> </ul> </li> </ul>							
<ul> <li>(2) Delete as appropriate.</li> <li>(3) Where:         <ul> <li>n = number of samples to be tested;</li> <li>m = threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria in all samples does not m;</li> </ul> </li> </ul>							
<ul> <li>(<sup>3</sup>) Where:</li> <li>n = number of samples to be tested;</li> <li>m = threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria in all samples does not m;</li> </ul>							
<ul> <li>n = number of samples to be tested;</li> <li>m = threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria in all samples does not m;</li> </ul>							
m = threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria in all samples does no m;							
m;							
M - movimum value for the number of besterie, the result is considered upsetisfectory if the number of besterie is an even even	ot exceed						
M = maximum value for the number of bacteria; the result is considered unsatisfactory if the number of bacteria in one or more sam or more; and	ples is M						
c = number of samples the bacterial count of which may be between m and M, the sample still being considered acceptable if the count of the other samples is m or less.	bacterial						
( <sup>4</sup> ) OJ L 147, 31.5.2001, p. 1.							
- The signature and the stamp must be in a different colour to that of the printing.							
— Note for the person responsible for the consignment in the European Union: This certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.							
Official veterinarian/Official inspector							
Name (in capital letters): Qualification and title:							
Date: Signature:							
Stamp:							

## CHAPTER 2(A)

## Health certificate

For milk, milk-based products and milk-derived products not intended for human consumption for dispatch to or transit through  $\binom{2}{1}$  the European Union

cou	DUNTRY Veterinary certifica					
	l.1.	Consignor	I.2. Certificate reference No I.2.a.			
		Name				
		Address	I.3. Central competent authority			
		Tel.	I.4. Local competent authority			
1	1.5.		I.6. Person responsible for the load in EU			
nen	1.0.	Name	Name			
ign		Address	Address			
Suo						
o p		Postcode	Postcode			
of dispatched consignment		Tel.	Tel.			
spat		Country of origin ISO code I.8. Region of origin Code	I.9. Country of ISO code I.10. Region of Code			
ğ	1.7.	Country of origin 100 code 1.8. Region of origin Code	destination destination			
s S						
Part I: Details	1.11.	Place of origin	I.12. Place of destination			
0						
art		Name Approval number	Name Custom warehouse			
<b>–</b>		Address Name Approval number	Address Approval number			
		Address	Postcode			
		Name Approval number Address				
	1.13.	Place of loading	I.14. Date of departure			
		······································				
	l.15.	Means of transport	I.16. Entry BIP in EU			
		Aeroplane Ship Railway wagon				
		Road vehicle  Other	I.17. Number(s) of CITES			
		Identification				
		Documentation references				
	I.18.	Description of commodity	I.19. Commodity code (HS code)			
			I.20. Quantity			
	1.21.	Temperature of product Ambient Chilled	I.22. Number of packages			
	123	Seal/Container No	I.24. Type of packaging			
	1.20.		1.24. Type of packaging			
	1.25.	Commodities certified for:				
		Animal feedingstuff	Technical use 🗖			
	1.26.	For transit through EU to third country	I.27. For import or admission into EU			
		Third country ISO code				
	1.28.	Identification of the commodities				
		Approval number of esta	ablishments			
		Species (Scientific name) Manufacturing pl				

# Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011. (See end of Document for details)

COUNTRY		NTRY			Milk, milk-based products and milk-derived products not for human consumption			
ſ		Ш.	Health information II.a. Certificate reference No II.b.					
			I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 of the European Parliam and of the Council ( <sup>1a</sup> ), and in particular Article 10 thereof, and Commission Regulation (EU) No 142/2011 ( <sup>1b</sup> ), and in particular Annex Chapter II, Section 4 and Annex XIV, Chapter I thereto, and certify that the milk ( <sup>2</sup> ), the milk-based products ( <sup>2</sup> ) and milk-deriv products ( <sup>2</sup> ) referred to in box 1.28 comply with the following conditions:					
	rtification	II.1.	which is list	ted in the Ar	derived in			
					raw milk derived from animals which at the time of milking did not show clinical signs of any disease transmissible r animals, and which had been kept for at least 30 days prior to production on holdings that were not subject to foot-and-mouth disease or rinderpest;			
		II.3.	they are mill	hey are milk or milk products that:				
			(2) either [have undergone one of the treatments or combinations thereof described in point II.4;]					
			( <sup>2</sup> ) or [comprise whey to be fed to animals of species susceptible to foot-and-mouth disease, and that whey was collected from mill subjected to one of the treatments described in point II.4 and:					
( <sup>2</sup> ) either [the whey was collected at least 16 hours after clotti				(2) either	[the whey was collected at least 16 hours after clotting and has a pH below 6;]			
( <sup>2</sup> )( <sup>4</sup> ) or [the whey has been produced at least 21 days before have been detected in the exporting country;]				( <sup>2</sup> )( <sup>4</sup> ) or	[the whey has been produced at least 21 days before the shipping and during that period no cases of FMD have been detected in the exporting country;]			
				[the whey has been produced on/, this date, in consideration of the foreseen voyage duration, being at least 21 days before the consignment is presented to a border inspection post of the European Union;]]				
		II.4.	4. they have been subject to one of the following treatments:					
( <sup>2</sup> ) either [High Temperature Short Time pasteurisation at 72 °C for at least 15 see negative reaction to a phosphatase test in bovine milk, in combination with the second s			erature Short Time pasteurisation at 72 °C for at least 15 seconds, or an equivalent pasteurisation achieving a cition to a phosphatase test in bovine milk, in combination with:					
		( <sup>2</sup> ) either	[a subsequent second High Temperature Short Time pasteurisation at 72 °C for at least 15 seconds or an equivalent pasteurisation which itself achieves a negative reaction to a phosphatase test in bovine milk;]					
( <sup>2</sup> ) or [a subsequent drying process that in the case of n 72 °C or higher;]		(²) or	[a subsequent drying process that in the case of milk intended for feeding is combined with additional heating to 72 $^\circ C$ or higher;]					
		( <sup>2</sup> ) or [a subsequent process by which the pH is reduced and kept for at least one hour		[a subsequent process by which the pH is reduced and kept for at least one hour at a level below 6;]				
		( <sup>2</sup> )( <sup>4</sup> ) or	[the condition that the milk/milk product has been produced at least 21 days before the shipping and during that period no cases of FMD have been detected in the exporting country;]					
		( <sup>2</sup> )( <sup>4</sup> ) or	[the milk/milk product has been produced on//, this date, in consideration of the foreseen voyage duration, being at least 21 days before the consignment is presented to a border inspection post of the European Union;]					
				(²) or	[sterilisation at a level of at least $F_03$ ;]]			
		( <sup>2</sup> ) or [Ultra High Temperature treatment at 132 °C for at least one second in combination with:		Temperature treatment at 132 °C for at least one second in combination with:				
				( <sup>2</sup> ) either	[a subsequent drying process that in the case of milk intended for feeding is combined with additional heating to 72 °C or higher;]			
				(²) or	[a subsequent process by which the pH is reduced and kept for at least one hour at a level below 6;]			
				( <sup>2</sup> )( <sup>4</sup> ) or	[the condition that the milk/milk product has been produced at least 21 days before the shipping and during that period no cases of FMD has been detected in the exporting country;]			
				( <sup>2</sup> )( <sup>4</sup> ) or	[the milk/milk product has been produced on//, this date, in consideration of the foreseen voyage duration, being at least 21 days before the consignment is presented to a border inspection post of the European Union;]]			

COUNTRY Milk, milk-based products and milk-derived products not for human consumpti							
۱۱.	Health info	rmation II.a. Certificate reference No II.b.					
II.5.	every precaution was taken to avoid contamination of the milk/milk-based product/milk-derived product after processing;						
II.6.	the milk/milk-based product/milk-derived product was packed:						
	( <sup>2</sup> ) either [in new containers;]						
	( <sup>2</sup> ) or [in vehicles or bulk containers disinfected prior to loading using a product approved by the competent authority;]						
	and the containers are marked so as to indicate the nature of the milk/milk-based product/milk-derived product and bear labels indicating that the product is Category 3 material and not intended for human consumption;						
11.7.							
	( <sup>2</sup> ) either [the product does not contain and is not derived from specified risk material as defined in Annex V to Regulation (EC) No 999/2001 of the European Parliament and of the Council ( <sup>5</sup> ) or mechanically separated meat obtained from bones of bovine, ovine or caprine animals; and the animals from which this product is derived have not been slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity;]						
	( <sup>2</sup> ) or [the product does not contain and is not derived from bovine, ovine or caprine materials other than those derived fro animals born, continuously reared and slaughtered in a country or region classified as posing a negligible BSE risk by decision in accordance with Article 5(2) of Regulation (EC) No 999/2001;]						
II.8.	in addition a	as regards TSE:					
	( <sup>2</sup> ) either [in case of animal by-products intended for feeding ruminants and containing milk or milk products of ovine or caprine origin, the ovine and caprine animals from which these products are derived have been kept continuously since birth or for the last three years on a holding where no official movement restriction is imposed due to a suspicion of TSE and which has satisfied the following requirements for the last three years:						
	(i) it has been subject to regular official veterinary checks;						
		<ul> <li>(ii) no classical scrapie case, as defined in point 2(g) of Annex I to Regulation (EC) No 999/2001, has been diagnosed or, following the confirmation of a classical scrapie case:</li> </ul>					
	- all animals in which classical scrapie was confirmed have been killed and destroyed, and						
		<ul> <li>all goats and sheep on the holding have been killed and destroyed, except for breeding rams of the ARR/ARR genotype and breeding ewes carrying at least one ARR allele and no VRQ allele;</li> </ul>					
		(iii) ovine and caprine animals, with the exception of sheep of the ARR/ARR prion genotype, are introduced into the holding only if they come from a holding which complies with the requirements set out in points (i) and (ii).]					
	( <sup>2</sup> ) or	[in case of animal by-products intended for feeding ruminants and containing milk or milk products of ovine or caprine origin, and destined to a Member State listed in the Annex to Commission Regulation (EC) No 546/2006 <sup>(6)</sup> , the ovine and caprine animals from which these products are derived have been kept continuously since birth or for the last seven years on a holding where no official movement restriction is imposed due to a suspicion of TSE and which has satisfied the following requirements for the last seven years:					
		(i) it has been subject to regular official veterinary checks;					
		<ul> <li>(ii) no classical scrapie case, as defined in point 2(g) of Annex I to Regulation (EC) No 999/2001, has been diagnosed or, following the confirmation of a classical scrapie case:</li> </ul>					
		- all animals in which classical scrapie was confirmed have been killed and destroyed, and					
		<ul> <li>— all goats and sheep on the holding have been killed and destroyed, except for breeding rams of the ARR/ARR genotype and breeding ewes carrying at least one ARR allele and no VRQ allele,</li> </ul>					
		(iii) ovine and caprine animals, with the exception of sheep of the ARR/ARR prion genotype, are introduced into the holding only if they come from a holding which complies with the requirements set out in points (i) and (ii).]					
Notes							
Part I:							
- Box reference I.6: Person responsible for the load in the European Union: this box is to be filled in only if it is a certificate for transit commodity.							
— Вох	- Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity.						

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011. (See end of Document for details)

COUNTRY	Milk, milk-based products and milk-derived products not for human consumption					
II. Health information	II.a. Certificate reference No II.b.					
— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship) is to be provided. In case of unloading and reloading, the consignor must inform the border inspection post of the European Union.						
- Box reference I.19: use the appropriate Harmonised System (HS) code of the World Customs Organisation: 23.09.10, 23.09.90, 35.01, 35.02 or 35.04.						
- Box reference I.23: for bulk containers, the containe	r number and the seal number (if applicable) must be included.					
- Box reference I.25: technical use: any use other that	n for animal consumption.					
- Box reference I.26 and I.27: fill in according to whet	her it is a transit or an import certificate.					
- Box reference I.28: 'Manufacturing plant': provide the	e registration number of treatment or processing establishment.					
Part II:						
( <sup>1a</sup> ) OJ L 300, 14.11.2009, p. 1.						
( <sup>1b</sup> ) OJ L 54, 26.2.2011, p. 1.						
( <sup>2</sup> ) Delete as appropriate.						
(3) For completion if the authorisation to import into th	e European Union is restricted to certain regions of the third country concerned.					
(4) this condition applies only to third countries listed i	n column 'A' of Annex I to Regulation (EU) No 605/2010.					
( <sup>5</sup> ) OJ L 147, 31.5.2001, p. 1.						
( <sup>6</sup> ) OJ L 94, 1.4.2006, p. 28.						
- The signature and the seal must be in a different co	lour from that of the printing.					
<ul> <li>Note for the importer: this certificate is only for veterinary purposes and must accompany the consignment until it reaches the border inspection post of the European Union.</li> </ul>						
Official veterinarian/Official inspector						
Name (in capital letters):	Qualification and title:					
Date:	Signature:					
Stamp:						

## CHAPTER 2(B)

## Health certificate

For colostrum and colostrum products from bovine animals not intended for human consumption for dispatch to or transit through  $\binom{2}{}$  the European Union

cou	NTRY	,	Veterinary certificate to EU		
	l.1.	Consignor	I.2. Certificate reference No I.2.a.		
		Name			
		Address	I.3. Central competent authority		
		Tel.	I.4. Local competent authority		
Ħ	1.5.	Consignee	I.6. Person responsible for the load in EU		
ame		Name	Name		
sigr		Address	Address		
S		Postcode	Postcode		
hed		Tel.	Tel.		
patc					
dis	1.7.	Country of origin ISO code I.8. Region of origin Code	I.9. Country of ISO code I.10. Region of Code destination		
s of					
Part I: Details of dispatched consignment	1.11.	Place of origin	I.12. Place of destination		
Ď					
art		Name Approval number Address	Name Custom warehouse		
		Name Approval number	Address Approval number		
		Address	Postcode		
		Name Approval number Address			
	l.13.	Place of loading	I.14. Date of departure		
	l.15.	Means of transport	I.16. Entry BIP in EU		
		Aeroplane 🗌 Ship 🗌 Railway wagon 🗌	I.17. Number(s) of CITES		
		Road vehicle Other			
		Identification			
		Documentation references			
	l.18.	Description of commodity	I.19. Commodity code (HS code)		
			I.20. Quantity		
	1.21.	Temperature of product Ambient Chilled	Frozen		
	1.02	Ambient Chilled Seal/Container No	—		
	1.23.	Searcondiner No	I.24. Type of packaging		
	1.25.	Commodities certified for:			
		Animal feedingstuff	Technical use		
	1.26.	For transit through EU to third country	I.27. For import or admission into EU		
		Third country ISO code			
	1.28.	Identification of the commodities			
	(	Species Approval number of establishments Scientific name) Manufacturing plant	Net weight Batch number		

# Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011. (See end of Document for details)

co	UNTRY	Colostrum and colostrum products from bovine animals not for human consumption				
	П.	Health infor	mation		II.a. Certificate reference No	II.b.
		I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 of the European Parliament and of the Council ( <sup>1a</sup> ), and in particular Article 10 thereof, and Commission Regulation (EU) No 142/2011 ( <sup>1b</sup> ), and in particular Annex X, Chapter II, Section 4 and Annex XIV, Chapter I thereto, and certify that the colostrum ( <sup>2</sup> ) or the colostrum products ( <sup>2</sup> ) referred to in box 1.28 comply with the following conditions: they were produced and derived in				
rtification	II.1.					
Part II: Certification	II.2. they were produced from colostrum derived from animals which at the time of milking did not show clinical signs of any dise transmissible through colostrum to humans or animals, and which had been kept for at least 30 days prior to production on holdi that were not subject to official restrictions due to foot-and-mouth disease or rinderpest;					
	II.3.	they are colostrum or colostrum products of bovine animals that have been subject to High Temperature Short Time pasteurisation at 72 °C for at least 15 seconds, or an equivalent pasteurisation achieving a negative reaction to a phosphatase test in bovine milk, in combination with:				
		( <sup>2</sup> )( <sup>4</sup> ) either [the condition that the colostrum or colostrum products have been produced at least 21 days before the shipping and in this period no cases of FMD have been detected in the exporting country;]				
		( <sup>2</sup> )( <sup>4</sup> ) or [the colostrum or colostrum products have been produced on/, this date, in consideration of the foreseen voyage duration, being at least 21 days before the consignment is presented to a border inspection post of the European Union;				
		and have been obtained from animals subject to regular veterinary inspections to ensure that they come from holdings on whi all bovine herds are:			they come from holdings on which	
		( <sup>2</sup> )( <sup>4</sup> ) either [recognised as officially tuberculosis and brucellosis free ( <sup>5</sup> ),]				
		( <sup>2</sup> )( <sup>4</sup> ) or [not restricted under the national legislation of the third country of origin regarding eradication of tubercule and brucellosis,]				garding eradication of tuberculosis
and $\binom{2}{4}$ either [recognised as official enzootic-bovine-leukosis free $\binom{5}{3}$ ]						
		( <sup>2</sup> )( <sup>4</sup> ) or [included in an official system for the control of enzootic bovine leukosis and there has been no evidence result of clinical and laboratory testing of this disease in the herd during the past two years;]				
	II.4.	every precau	every precaution was taken to avoid contamination of the colostrum/colostrum product after processing;			
	II.5.	the colostrur	the colostrum/colostrum product was packed:			
		( <sup>2</sup> ) either [in new containers,]				
		( <sup>2</sup> ) or [in vehicles or bulk containers disinfected prior to loading using a product approved by the competent authority,]			the competent authority,]	
		and the containers are marked so as to indicate the nature of the colostrum/colostrum product and bear labels indicating that the product is Category 3 material and not intended for human consumption;				t and bear labels indicating that the
	II.6.					
		( <sup>2</sup> ) either [the product does not contain and is not derived from specified risk material as defined in Annex V to Regulation (EC) No 999/2001 of the European Parliament and of the Council ( <sup>6</sup> ) or mechanically separated meat obtained from bones of bovine, ovine or caprine animals; and the animals from which this product is derived have not been slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity;]			ated meat obtained from bones of not been slaughtered after stunning red by laceration of central nervous	
		(2) or [the product does not contain and is not derived from bovine, ovine or caprine materials other than those derived from animals born, continuously reared and slaughtered in a country or region classified as posing a negligible BSE risk by a decision in accordance with Article 5(2) of Regulation (EC) No 999/2001;]				
	11.7.	in addition a	s regards TSI	E:		
		( <sup>2</sup> ) either	the ovine and three years o	nimal by-products intended for feeding d caprine animals from which these pro n a holding where no official movement requirements for the last three years:	oducts are derived have been kept con t restriction is imposed due to a suspic	ntinuously since birth or for the last
		(i) it has been subject to regular official veterinary checks;				

Ш.	Health inf	formation	II.a. Certificate reference No	II.b.				
		(ii) no classical scrapie case, as defined in point 2(g) of Annex I to Regulation (EC) No 999/2001, has been diagnosed or, following the confirmation of a classical scrapie case:						
	- all animals in which classical scrapie was confirmed have been killed and destroyed, and							
<ul> <li>— all goats and sheep on the holding have been killed and destroyed, except for breeding genotype and breeding ewes carrying at least one ARR allele and no VRQ allele;</li> </ul>								
			exception of sheep of the ARR/ARR prion hich complies with the requirements set of					
	(²) or	and destined to a Member State listed i animals from which these products are	for feeding ruminants and containing milk in the Annex to Commission Regulation (E derived have been kept continuously sir triction is imposed due to a suspicion of	C) No 546/2006 ( <sup>7</sup> ), the ovine and caprin nce birth or for the last seven years on				
		(i) it has been subject to regular officia	al veterinary checks;					
		<ul> <li>(ii) no classical scrapie case, as define following the confirmation of a class</li> </ul>	ed in point 2(g) of Annex I to Regulation (E sical scrapie case:	EC) No 999/2001, has been diagnosed o				
		- all animals in which classical sc	rapie was confirmed have been killed and	destroyed, and				
			lding have been killed and destroyed, ex arrying at least one ARR allele and no VR					
			exception of sheep of the ARR/ARR prion hich complies with the requirements set of					
Notes								
Part I	:							
— Во	x reference I	I.6: Person responsible for the load in the E	uropean Union: this box is to be filled in on	nly if it is a certificate for transit commodit				
— Во	x reference	I.12: Place of destination: this box is to be	filled in only if it is a certificate for transit	commodity.				
		I.15: Registration number (railway wagons ing and reloading, the consignor must infor						
	x reference I .04.	.19: use the appropriate Harmonised System	m (HS) code of the World Customs Organi	sation: 23.09.10, 23.09.90, 35.01, 35.02				
— Во	x reference	I.23: for bulk containers, the container num	ber and the seal number (if applicable) m	nust be included.				
— Во	x reference	I.25: technical use: any use other than for	animal consumption.					
— Во	x reference	I.26 and I.27: fill in according to whether it	is a transit or an import certificate.					
— Во	x reference	I.28: 'Manufacturing plant': provide the regi	stration number of treatment or processing	g establishment.				
Part I	l:							
<sup>1a</sup> ) C	J L 300, 14	.11.2009, p. 1.						
<sup>(1b</sup> ) C	J L 54, 26.2	2.2011, p. 1.						
<sup>2</sup> ) D	elete as app	propriate.						
<sup>3</sup> ) F	or completio	n if the authorisation to import into the Eur	opean Union is restricted to certain region	ns of the third country concerned.				
( <sup>4</sup> ) th	nis condition	applies only to third countries listed in colu	umn 'A' of Annex I to Commission Regula	tion (EU) No 605/2010.				
		rculosis and brucellosis free herd as laid herd as laid down in Chapter I of Annex D		4/432/EEC; and officially enzootic-bovin				
( <sup>6</sup> ) C	OJ L 147, 31.5.2001, p. 1.							
(7) C		2006, p. 28.						

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011. (See end of Document for details)

COUNTRY	Colostrum and c	olostrum products from bovine ani	mals not for human consumption					
II. Health	h information	II.a. Certificate reference No	II.b.					
— The signatu	- The signature and the seal must be in a different colour from that of the printing.							
	<ul> <li>Note for the importer: this certificate is only for veterinary purposes and must accompany the consignment until it reaches the border inspection post of the European Union.</li> </ul>							
Official veterina	Official veterinarian/Official inspector							
Name (in	capital letters):	Qualification a	and title:					
Date:		Signature:						
Stamp:								

## CHAPTER 3(A)

## Health certificate

For canned petfood intended for dispatch to or for transit through (<sup>2</sup>) the European Union

cou	NTRY	,	Veterinary certificate to EU		
	l.1.	Consignor	I.2. Certificate reference No I.2.a.		
		Name			
		Address	I.3. Central competent authority		
		Tel.	I.4. Local competent authority		
Ħ	1.5.	Consignee	I.6. Person responsible for the load in EU		
ame		Name	Name		
sigr		Address	Address		
S		Postcode	Postcode		
per		Tel.	Tel.		
dispatched consignment					
disp	1.7.	Country of origin ISO code I.8. Region of origin Code	I.9. Country of ISO code I.10. Region of Code		
5			destination destination		
ails		Place of science			
Det		Place of origin	I.12. Place of destination		
Part I: Details of		Name Approval number	Name Custom warehouse		
Ра		Address	Address Approval number		
		Name Approval number Address			
		Name Approval number	Postcode		
	1.12	Address Place of loading	I.14. Date of departure		
	1.13.	Place of loading	1.14. Date of departure		
	I.15.	Means of transport	I.16. Entry BIP in EU		
		Aeroplane 🗌 Ship 🗌 Railway wagon 🗌			
		Road vehicle Other	1.17.		
		Identification			
		Documentation references			
	I.18.	Description of commodity	I.19. Commodity code (HS code)		
			23.09.10		
			I.20. Quantity		
	1.21.	Temperature of product	I.22. Number of packages		
		Ambient Chilled	Frozen		
	1.23.	Seal/Container No	I.24. Type of packaging		
	1.25.	Commodities certified for:	1		
		Animal feedingstuff			
	1.26.	For transit through EU to third country	I.27. For import or admission into EU		
		Third country ISO code			
	1.28.	Identification of the commodities			
		Species Approval number of establishme (Scientific name) Manufacturing plant	ents Net weight Batch number		

co	COUNTRY Canned Pet						
	П.	Health information	II.a. Certificate reference No	II.b.			
		I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 of the European Parliament and of the Council ( <sup>1a</sup> ) and in particular Articles 8 and 10 thereof, and Commission Regulation (EU) No 142/2011 ( <sup>1b</sup> ), and in particular Annex XIII, Chapter II and Annex XIV, Chapter II, thereof and certify that the petfood described above:					
lication	II.1.	has been prepared and stored in an establishment or plant approved and supervised by the competent authority in accordance with Article 24 of Regulation (EC) No 1069/2009;					
Certi	11.2.	has been prepared exclusively with the following animal by-products:					
Part II: Certification	( <sup>2</sup> ) either [- carcases and parts of animals slaughtered or, in the case of game, bodies or parts of animals killed, and whic human consumption in accordance with Union legislation, but are not intended for human consumption for reasons.]						
	( <sup>2</sup> ) and/or [- carcases and the following parts originating either from animals that have been slaughtered in a slaughterhouse an considered fit for slaughter for human consumption following an ante-mortem inspection or bodies and the following p animals from game killed for human consumption in accordance with Union legislation:						
	-	<ul> <li>(i) carcases or bodies and parts of animals wh legislation, but which did not show any sign</li> </ul>					
		(ii) heads of poultry;					
		<ul><li>(iii) hides and skins, including trimmings and sp metacarpus bones, tarsus and metatarsus b</li></ul>					
		(iv) pig bristles;					
		(v) feathers;]					
( <sup>2</sup> ) and/or [- blood of animals which did not show any signs of disease communicable through blood to humans or animals, animals other than ruminants that have been slaughtered in a slaughterhouse after having been considered fit for human consumption following an ante-mortem inspection in accordance with Union legislation;]							
		( <sup>2</sup> ) and/or [- animal by-products arising from the production greaves and centrifuge or separator sludge from		mption, including degreased bone,			
		( <sup>2</sup> ) and/or [- products of animal origin, or foodstuffs contair consumption for commercial reasons or due to which no risk to public or animal health arise;]					
		( <sup>2</sup> ) and/or [- petfood and feedingstuffs of animal origin, or feeding for commercial reading for commercial reading for commercial reading for commercial reading for the public or animal has been been been been been been been bee	sons or due to problems of manufactu				
		( <sup>2</sup> ) and/or [- blood, placenta, wool, feathers, hair, horns, hool any disease communicable through that product		animals that did not show signs of			
		( <sup>2</sup> ) and/or [- aquatic animals, and parts of such animals, exce to humans or animals;]	pt sea mammals, which did not show a	ny signs of diseases communicable			
	( <sup>2</sup> ) and/or [- animal by-products from aquatic animals originating from plants or establishments manufacturing products for consumption;]						
	( <sup>2</sup> ) and/or [- the following material originating from animals which did not show any signs of disease communicable through that m to humans or animals:						
		(i) shells from shellfish with soft tissue or flesh					
		(ii) the following originating from terrestrial anim	als:				
		<ul> <li>hatchery by-products,</li> </ul>					
		— eggs,					
		<ul> <li>egg by-products, including egg shells;</li> </ul>					
	(iii) day-old chicks killed for commercial reasons;]						

COUN	TRY			Canned Petfood
П.	Health information	tion	II.a. Certificate reference No	II.b.
	( <sup>2</sup> ) and/or	- animal by-products from aquatic or terrestrial	invertebrates other than species path	ogenic to humans or animals;]
	( <sup>2</sup> ) and/or	[- material from animals which have been trea 96/22/EC, the import of the material bein No 1069/2009;]		
II.3.	has been su	bjected to heat treatment to a minimum Fc valu	ue of 3 in hermetically sealed containe	ers;
II.4.		d by a random sampling of at least five containe at treatment of the whole consignment as fores		ratory diagnostic methods to ensure
II.5.	has undergo	one all precautions to avoid contamination with p	pathogenic agents after treatment.	
II.6.				
	( <sup>2</sup> ) either	[the product does not contain and is not deriv No 999/2001 of the European Parliament and bovine, ovine or caprine animals; and the ani stunning by means of gas injected into the or central nervous tissue by means of an elonge	of the Council ( <sup>3</sup> ) or mechanically sepainals from which this product is derive ranial cavity or killed by the same met	arated meat obtained from bones of ed have not been slaughtered after hod or slaughtered by laceration of
	( <sup>2</sup> ) or	[the product does not contain and is not deriv animals born, continuously reared and slaught decision in accordance with Article 5(2) of Re	tered in a country or region classified a	
II.7.	in addition a	s regards TSE:		
	( <sup>2</sup> ) either	[in case of animal by-products intended for fe origin, the ovine and caprine animals from whi for the last three years on a holding where no which has satisfied the following requirements	ich these products are derived have b o official movement restriction is impo	een kept continuously since birth or
		(i) it has been subject to regular official vete	rinary checks;	
		<ul> <li>(ii) no classical scrapie case, as defined in po or, following the confirmation of a classical</li> </ul>		No 999/2001, has been diagnosed
		- all animals in which classical scrapie	was confirmed have been killed and d	lestroyed, and
		<ul> <li>all goats and sheep on the holding ha genotype and breeding ewes carrying</li> </ul>		
		(iii) ovine and caprine animals, with the exce holding only if they come from a holding		
	( <sup>2</sup> ) or	[in case of animal by-products intended for fe origin, and destined to a Member State listed and caprine animals from which these product years on a holding where no official movemen the following requirements for the last seven	in the Annex to Commission Regulati s are derived have been kept continuo t restriction is imposed due to a suspice	on (EC) No 546/2006 ( <sup>4</sup> ), the ovine usly since birth or for the last seven
		(i) it has been subject to regular official vete	rinary checks;	
		<ul> <li>(ii) no classical scrapie case, as defined in po or, following the confirmation of a classical</li> </ul>		No 999/2001, has been diagnosed
		- all animals in which classical scrapie	was confirmed have been killed and d	lestroyed, and
		<ul> <li>all goats and sheep on the holding ha genotype and breeding ewes carrying</li> </ul>		
		<li>(iii) ovine and caprine animals, with the exce holding only if they come from a holding</li>		

### **Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011. (See end of Document for details)

COUNTRY Canned Petfood					
II. Health information	II.a. Certificate reference No	II.b.			
Notes					
Part I:					
<ul> <li>Box reference I.6: Person responsible for the consignment in the Eu commodity; it may be filled in if the certificate is for import commod</li> </ul>		n only if it is a certificate for transit			
<ul> <li>Box reference I.12: Place of destination: this box is to be filled in only be stored in free zones, free warehouses and custom warehouses.</li> </ul>	y if it is a certificate for transit commod	ity. The products in transit can only			
<ul> <li>Box reference I.15: Registration number (railway wagons or containe provided in the event of unloading and reloading.</li> </ul>	er and lorries), flight number (aircraft) o	or name (ship); information is to be			
- Box reference I.23: for bulk containers, the container number and the	e seal number (if applicable) should b	e given.			
- Box reference I.25: technical use: any use other than for animal cor	sumption.				
- Box reference I.26 and I.27: fill in according to whether it is a transit	t or an import certificate.				
Part II:					
( <sup>1a</sup> ) OJ L 300, 14.11.2009, p. 1.					
( <sup>1b</sup> ) OJ L 54, 26.2.2011, p. 1.					
<ul> <li>(2) Delete as appropriate.</li> </ul>					
( <sup>3</sup> ) OJ L 147, 31.5.2001, p. 1.					
( <sup>4</sup> ) OJ L 94, 1,4,2006, p. 28.					
<ul> <li>The signature and the stamp must be in a different colour to that of</li> </ul>	the printing.				
<ul> <li>Note for the person responsible for the consignment in the Europ accompany the consignment until it reaches the border inspection p</li> </ul>	bean Union: This certificate is only fo	or veterinary purposes and has to			
Official veterinarian/Official inspector					
Name (in capital letters):	Qualification	and title:			
Date:	Signature:				
Stamp:					

### [<sup>F1</sup>CHAPTER 3(B)

#### Health certificate

For processed petfood other than canned petfood, intended for dispatch to or for transit through  $\binom{2}{1}$  the European Union]

cou	NTR	Y	Veterinary certificate to EU		
	l.1.	Consignor	I.2. Certificate reference No I.2.a.		
		Name Address			
		Address	I.3. Central competent authority		
		Tel.	I.4. Local competent authority		
lent	1.5.	Consignee	I.6. Person responsible for the load in EU		
gnn		Name Address	Name Address		
onsi					
õp		Postcode Tel.	Postcode Tel.		
tche					
dispatched consignment	1.7.	Country of origin ISO code I.8. Region of origin Code	I.9. Country of ISO code I.10. Region of Code destination		
s of	1.4.4	Diago of origin	L12. Place of destination		
etail	1.11.	Place of origin			
Ď		Name Approval number Address	Name         Custom warehouse           Address         Approval number		
Part I: Details		Name Approval number			
•		Address	Postcode		
		Name Approval number Address			
	I.13.	Place of loading	I.14. Date of departure		
	l.15.	Means of transport	I.16. Entry BIP in EU		
		Aeroplane Ship Railway wagon			
		Road vehicle Other Other	1.17.		
		Identification			
		Documentation references			
	l.18.	Description of commodity	I.19. Commodity code (HS code)		
			I.20. Quantity		
	121	Temperature of product	I.22. Number of packages		
	1.21.	Ambient Chilled	Frozen		
	1.00	Seal/Container No			
	1.23.		I.24. Type of packaging		
	1.25.	Commodities certified for:	·		
		Animal feedingstuff Technical			
	1.26.	For transit through EU to third country	I.27. For import or admission into EU		
		Third country ISO code			
	1.28.	Identification of the commodities	1		
		Species Approval number of (Scientific name) Manufacturi			

COL	INTRY			Processed petfood other than canned petfoo				
	п.	Health info	rmat	tion II.a. Certificate reference No II.b.				
c	ed official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 of the European Parliamen neil ( <sup>1a</sup> ) and in particular Articles 8 and 10 thereof, and Commission Regulation (EU) No 142/2011 ( <sup>1b</sup> ), and in particular nex XIII and Chapter II of Annex XIV thereto and certify that the petfood described above:							
Part II: Certification	II.1.	has been prepared and stored in a plant approved and supervised by the competent authority in accordance with Article 24 of Regulation (EC) No 1069/2009;						
II: Cel	11.2.	red exclusively with the following animal by-products:						
( <sup>2</sup> ) either [- carcases and parts of animals slaughtered or, in the case of game, bodies or parts of animals killed, ar human consumption in accordance with Union legislation, but are not intended for human consumption reasons;]								
		(²) and/or	[-	carcases and the following parts originating either from animals that have been slaughtered in a slaughterhouse and were considered fit for slaughter for human consumption following an ante-mortem inspection or bodies and the following parts of animals from game killed for human consumption in accordance with Union legislation:				
	<ul> <li>(i) carcases or bodies and parts of animals which are rejected as unfit for human consumption in accordance with legislation, but which did not show any signs of disease communicable to humans or animals;</li> </ul>							
				(ii) heads of poultry;				
				<li>(iii) hides and skins, including trimmings and splitting thereof, horns and feet, including the phalanges and the carpus and metacarpus bones, tarsus and metatarsus bones;</li>				
				(iv) pig bristles;				
				(v) feathers;]				
		(2) and/or [- animal by-products from poultry and lagomorphs slaughtered on the farm as referred to in Article 1(3)(d) of Regula (EC) No 853/2004, which did not show any signs of disease communicable to humans or animals:]						
		(2) and/or [- blood of animals which did not show any signs of disease communicable through blood to humans or animals, obt from animals other than ruminants that have been slaughtered in a slaughterhouse after having been considered slaughter for human consumption following an ante-mortem inspection in accordance with Union legislation;]						
		(²) and/or	[-	animal by-products arising from the production of products intended for human consumption, including degreased bone greaves and centrifuge or separator sludge from milk processing;]				
		(²) and/or	[-	products of animal origin, or foodstuffs containing products of animal origin, which are no longer intended for humar consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arise;]				
		(²) and/or	[-	petfood and feedingstuffs of animal origin, or feedingstuffs containing animal by-products or derived products, which are no longer intended for feeding for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arises;]				
		(²) and/or	[-	blood, placenta, wool, feathers, hair, horns, hoof cuts and raw milk originating from live animals that did not show signs of any disease communicable through that product to humans or animals;]				
		(²) and/or	[-	aquatic animals, and parts of such animals, except sea mammals, which did not show any signs of diseases communicable to humans or animals;]				
		(²) and/or	[-	animal by-products from aquatic animals originating from plants or establishments manufacturing products for humar consumption;]				
		( <sup>2</sup> ) and/or [- the following material originating from animals which did not show any signs of disease communicable through that material to humans or animals:						
		(i) shells from shellfish with soft tissue or flesh;						
		(ii) the following originating from terrestrial animals:						
				— hatchery by-products,				
				— eggs,				
				<ul> <li>egg by-products, including egg shells;</li> </ul>				
				(iii) day-old chicks killed for commercial reasons;]				

		umation	Processed petfood other than can	neu perior
II.	Health info	rmation II.a. Ce	ertificate reference No II.b.	
	(²) and/or	[- animal by-products from aquatic or terrestrial invertebr	rates other than species pathogenic to humans or a	nimals;]
	(²) and/or	<ul> <li>animals and parts thereof of the zoological orders of R to in Article 8(a)(iii), (iv) and (v) of Regulation (EC) No 1 (g) of that Regulation;]</li> </ul>		
	(²) and/or	<ul> <li>material from animals which have been treated with 96/22/EC, the import of the material being permitte 1069/2009;]</li> </ul>		
II.3.				
	(²) either	[was subjected to a heat treatment of at least 90 $^{\circ}\mathrm{C}$ through	ughout its substance;]	
	(²) or	[was produced as regards ingredients of animal origin us	ing exclusively products which had been:	
		<ul> <li>(a) in the case of animal by-products or derived products least 90 °C throughout its substance;</li> </ul>	s from meat or meat products subjected to a heat tre	atment of
		(b) in the case of milk and milk based products,		
		<ul> <li>(i) if they are from third countries or parts of third c (EU) No 605/2010 (<sup>3</sup>) submitted to a pasteurisat</li> </ul>	ountries listed in column B of Annex I to Commission ion treatment sufficient to produce a negative phosp	
		<ul> <li>(ii) with a pH reduced to less than 6 from third countries or parts of third countries listed in column C of Ann Commission Regulation (EU) No 605/2010, first submitted to a pasteurisation treatment sufficient to proc negative phosphatase test;</li> </ul>		
		(iii) if they are from third countries or parts of third countries listed in column C of Annex I to Regulation 605/2010, submitted to a sterilisation process or a double heat treatment where each treatment was suf produce a negative phosphatase test on its own;		
		(iv) if they are from third countries or parts of third 605/2010, where there has been an outbreak of fr against foot-and-mouth disease has been carried	pot-and-mouth disease in the last 12 months or where	
		either		
		- a sterilisation process whereby an Fc value of	equal or greater than 3 is achieved	
		or		
			at least equal to that achieved by a pasteurisation p ifficient to produce a negative reaction to a phosp	
		either		
			t at least equal to that achieved by the initial heat tre ive reaction to a phosphatase test, followed, in the c ig process	
		or		
		— an acidification process such that the pH has	s been maintained at less than 6 for at least one ho	our;
		(c) in the case of gelatine, produced using a process that treatment with acid or alkali, followed by one or more necessary repeated, extraction by heat, followed by	rinses with subsequent adjustment of the pH and su	
		(d) in the case of hydrolysed protein produced using a contamination of raw Category 3 material, and, in the hides and skins produced in a processing plant ded with a molecular weight below 10000 Dalton and a brining, liming and intensive washing followed by:	case of hydrolysed protein entirely or partly derived fr icated only to hydrolysed protein production, using o	om rumina only mater
		<ul> <li>(i) exposure of the material to a pH of more than 1 and subsequently by heat treatment at more that</li> </ul>	1 for more than three hours at a temperature of more In 140 °C for 30 minutes at more than 3,6 bar; or	e than 80

COUNTRY		Processed petfood other than canned petfood			
١١.	Health inform	natio	n	II.a. Certificate reference No	II.b.
			<li>(ii) exposure of the material to a pH of 1 to 2 for 30 minutes at 3 bar;</li>	2, followed by a pH of more than 11, fo	ollowed by heat treatment at 140 °C
		(e) in the case of egg products submitted to any of the processing methods 1 to 5 or 7, as referred to in Chapter III of Annex IV to Regulation (EU) No 142/2011; or treated in accordance with Chapter II of Section X of Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council ( <sup>4</sup> );			
		(f) in the case of collagen submitted to a process ensuring that unprocessed Category 3 material is subjected to a treatment involving washing, pH adjustment using acid or alkali followed by one or more rinses, filtration and extrusion, the use of preservatives other than those permitted by Union legislation being prohibited;			
		(g) in the case of blood products, produced using any of the processing methods 1 to 5 or 7, as referred to in Chapter III of Annex IV to Regulation (EU) No 142/2011;			
		(h)	in the case of mammalian processed animal case of porcine blood, submitted to any of th heat treatment throughout its substance at a	e processing methods 1 to 5 or 7 prov	vided that in the case of method 7 a
		(i)	in the case of non-mammalian processed p methods 1 to 5 or 7 as referred to in Chapt		
		(i)	in the case of fishmeal submitted to any of the products complies with the microbiolog Regulation (EU) No 142/2011;		
		(k)	in the case of rendered fat, including fish oils the case of fish oil) as referred to in Chapter with Chapter II of Section XII of Annex III to be purified in such a way that the maximun weight;	III of Annex IV to Regulation (EU) No 1 Regulation (EC) No 853/2004; render	42/2011 or produced in accordance ed fats from ruminant animals must
		(I)	in the case of dicalcium phosphate produce	d by a process that	
			<ul> <li>ensures that all Category 3 bone-materi hydrochloric acid (at a minimum concent</li> </ul>		
			(ii) following the procedure under (i), applie precipitate of dicalcium phosphate at pl		noric liquor with lime, resulting in a
			<li>(iii) finally, air dries the precipitate of dica temperature between 30 °C and 65 °C;</li>	licium phosphate with inlet temperati	ure of 65 °C to 325 °C and end
		(m)	in the case of tricalcium phosphate produce	d by a process that ensures	
			<ul> <li>(i) that all Category 3 bone-material is finel than 14 mm);</li> </ul>	y crushed and degreased in counter-f	low with hot water (bone chips less
			(ii) continuous cooking with steam at 145 $^\circ$	C during 30 minutes at 4 bar;	
			(iii) separation of the protein broth from the	hydroxyapatite (tricalcium phosphate)	by centrifugation; and
			(iv) granulation of the tricalcium phosphate	after drying in a fluid bed with air at 2	200 °C ;
		(n)	in the case of flavouring innards, produced product complies with the microbiological st		parameters, which ensure that the
	(²) or	[wa	s subject to a treatment such as drying or	fermentation, which has been author	rised by the competent authority;]
	(²) or	trea	the case of aquatic and terrestrial invertebrat trment which has been authorised by the cceptable risks to public and animal health;]		
II.4.			a random sampling of at least five samples from swith the following standards $(5)$ :	om each processed batch taken during	g or after storage at the processing
	Salmonella:		absence in 25g: n = 5, c = 0, m = 0, M =	= 0,	
	Enterobacteria	aceae	e: n = 5, c = 2, m = 10, M = 300 in 1 gram	ç	

COUNTRY Processed petfood other than canned pe				etfood other than canned petfood		
П.	Health infor	mation	II.a. Certificate reference No	II.b.		
II.5.	has undergo	ne all precautions to avoid contamination with path	ogenic agents after treatment;			
II.6.	was packed in new packaging, which, if the petfood is not dispatched in ready-to-sell packages on which it is clearly indicated that the content is destined for feeding to pets only, bear labels indicating "NOT FOR HUMAN CONSUMPTION";					
11.7.						
	(²) either	[the product does not contain and is not derived 999/2001 of the European Parliament and of the ( ovine or caprine animals; and the animals from v means of gas injected into the cranial cavity or k tissue by means of an elongated rod-shaped inst	Council ( <sup>6</sup> ) or mechanically separated n vhich this product is derived have not illed by the same method or slaughter	neat obtained from bones of bovine, been slaughtered after stunning by ed by laceration of central nervous		
	(²) or	[the product does not contain and is not deriver animals born, continuously reared and slaughter decision in accordance with Article 5(2) of Regul	ed in a country or region classified as			
II.8.	in addition as	s regards TSE:				
	(²) either	[in case of animal by-products intended for feedin the ovine and caprine animals from which these p three years on a holding where no official move satisfied the following requirements for the last th	products are derived have been kept co ement restriction is imposed due to a	ontinuously since birth or for the last		
		(i) it has been subject to regular official veterina	ary checks;			
		<ul> <li>(ii) no classical scrapie case, as defined in point following the confirmation of a classical scrap</li> </ul>		999/2001, has been diagnosed or,		
		- all animals in which classical scrapie was	confirmed have been killed and dest	royed, and		
		<ul> <li>all goats and sheep on the holding have genotype and breeding ewes carrying at</li> </ul>				
		<li>(iii) ovine and caprine animals, with the exception only if they come from a holding which comp</li>				
	(²) or	[in case of animal by-products intended for feedin and destined to a Member State listed in the Ann animals from which these products are derived it holding where no official movement restriction is requirements for the last seven years:	ex to Commission Regulation (EC) No have been kept continuously since bir	546/2006 (7), the ovine and caprine th or for the last seven years on a		
		(i) it has been subject to regular official veterina	ary checks;			
		<ul> <li>(ii) no classical scrapie case, as defined in point following the confirmation of a classical scrap</li> </ul>		999/2001, has been diagnosed or,		
		- all animals in which classical scrapie was	confirmed have been killed and dest	royed, and		
		<ul> <li>all goats and sheep on the holding have genotype and breeding ewes carrying at</li> </ul>				
		<li>(iii) ovine and caprine animals, with the exception only if they come from a holding which comp</li>				
Notes						
Part I:						
— Box	k reference I.6: nmodity; it may	Person responsible for the consignment in the Eu / be filled in if the certificate is for import commod	ropean Union: this box is to be filled i ity.	n only if it is a certificate for transit		
		2: Place of destination: this box is to be filled in only zones, free warehouses and custom warehouses.	y if it is a certificate for transit commod	ity. The products in transit can only		

### Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011. (See end of Document for details)

cou	INTRY	Processed p	etfood other than canned petfood		
П.	Health information	II.a. Certificate reference No	II.b.		
	Box reference I.15: Registration number (railway wagons or conta case of unloading and reloading, the consignor must inform the E		or name (ship) is to be provided. In		
	- Box reference I.19: use the appropriate Harmonized System (HS) code under the following headings: 04.08, 05.04, 05.05, 05.11, 15.01, 15.02, 15.03, 15.04, 23.01, 23.09 or 35.02.				
- 1	Box reference I.23: for bulk containers, the container number and	the seal number (if applicable) should b	e given.		
- 1	Box reference I.25: technical use: any use other than for animal o	onsumption.			
- 1	Box reference I.26 and I.27: fill in according to whether it is a tra	nsit or an import certificate.			
- 1	Box reference I.28: Species: select from the following: Aves, Man	nmalia - Ruminantia, Pesca, Mollusca, C	rustacea, Invertebrata.		
Par	t II:				
( <sup>1a</sup> )	OJ L 300, 14.11.2009, p. 1.				
( <sup>1b</sup> )	OJ L 54, 26.2.2011, p. 1.				
(²)	Delete as appropriate.				
(3)	OJ L 175, 10.7.2010, p. 1.				
(4)	OJ L 139, 30.4.2004, p. 55.				
(5)	Where:				
	n = number of samples to be tested;				
	m = threshold value for the number of bacteria; the result is con m;	sidered satisfactory if the number of bact	eria in all samples does not exceed		
	M = maximum value for the number of bacteria; the result is con or more; and	sidered unsatisfactory if the number of ba	acteria in one or more samples is M		
	c = number of samples the bacterial count of which may be be count of the other samples is m or less.	ween m and M, the sample still being co	insidered acceptable if the bacterial		
( <sup>6</sup> )	OJ L 147, 31.5.2001, p. 1.				
(7)	OJ L 94, 1.4.2006, p. 28.				
- ·	The signature and the stamp must be in a different colour to that	of the printing.			
	Note for the person responsible for the consignment in the European Union: This certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.				
Offi	cial veterinarian/Official inspector				
I	Name (in capital letters):	Qualifica	tion and title:		
I	Date:	Signature	9:		
:	Stamp:				

### CHAPTER 3(C)

#### Health certificate

For dogchews intended for dispatch to or for transit through  $(^{2})$  the European Union

ou	NTRY	,	Veterinary certificate to EU		
	l.1.	Consignor	I.2. Certificate reference No I.2.a.		
		Name			
		Address	I.3. Central competent authority		
		Tel.	I.4. Local competent authority		
ŧ	1.5.	Consignee	I.6. Person responsible for the load in EU		
me		Name	Name		
Isigi		Address	Address		
ç		Postcode	Postcode		
hed		Tel.	Tel.		
dispatched consignment					
dis	1.7.	Country of origin ISO code I.8. Region of origin Code	I.9. Country of ISO code I.10. Region of Code destination		
s of					
Part I: Details of	1.11.	Place of origin	I.12. Place of destination		
ם ∷					
Part		Name Approval number	Name         Custom warehouse           Address         Approval number		
		Name Approval number			
		Address Name Approval number	Postcode		
		Address			
	1.13.	Place of loading	I.14. Date of departure		
	1.15.	Means of transport	I.16. Entry BIP in EU		
		Aeroplane Ship Railway wagon			
		Road vehicle Other I Identification	1.17.		
		Documentation references			
	118	Description of commodity	I.19. Commodity code (HS code)		
			42.05.00		
			I.20. Quantity		
	1.21	Temperature of product	I.22. Number of packages		
		Ambient Chilled	Frozen		
	1.23.	Seal/Container No	I.24. Type of packaging		
	1.25.	Commodities certified for:	1		
		Animal feedingstuff			
	1.26.	For transit through EU to third country	I.27. For import or admission into EU		
		Third country ISO code			
	1.28.	Identification of the commodities			
		Species Approval number of establishments	Net weight Batch number		
	(	Scientific name) Manufacturing plant	-		

co	COUNTRY Dogchew									
	II.	Health information	II.a. Certificate reference No	II.b.						
	9/2009 of the European Parliament and in particular Annex XIII, Chapter									
ion	II.1.	have been prepared exclusively with the following animal by-products:								
Part II: Certification		( <sup>2</sup> ) either [- carcases and parts of animals slaughtered or, in the case of game, bodies or parts of animals killed, and which a human consumption in accordance with Union legislation, but are not intended for human consumption for cor reasons:]								
Part I		( <sup>2</sup> ) and/or [- carcases and the following parts originating either from animals that have been slaughtered in a slaughterhouse a considered fit for slaughter for human consumption following an ante-mortem inspection or bodies and the following animals from game killed for human consumption in accordance with Union legislation:								
		<ul> <li>(i) carcases or bodies and parts of animals whic legislation, but which did not show any signs</li> </ul>								
		(ii) heads of poultry;								
	(iii) hides and skins, including trimmings and splitting thereof, horns and feet, including the phalanges and the carpus metacarpus bones, tarsus and metatarsus bones, of animals other than ruminants;									
	(iv) pig bristles;									
	(v) feathers;]									
		( <sup>2</sup> ) and/or [- blood of animals which did not show any signs of o animals other than ruminants that have been slaus for human consumption following an ante-mortem	ng been considered fit for slaughter							
		( <sup>2</sup> ) and/or [- animal by-products arising from the production o greaves and centrifuge or separator sludge from	mption, including degreased bone,							
		( <sup>2</sup> ) and/or [- animal by-products from aquatic animals origina consumption;]	ting from plants or establishments n	nanufacturing products for human						
		( <sup>2</sup> ) and/or [- material from animals which have been treated wit the import of the material being permitted in account the import of the material being permitted in account the import of the material being permitted in account the import of the material being permitted in account the import of the material being permitted in account the import of the material being permitted in account the import of the material being permitted in account the import of the material being permitted in account the import of the material being permitted in account the materia								
	II.2.	have been subjected								
		( <sup>2</sup> ) either [in the case of dogchews made from hides and skin organisms (including salmonella); and the dogchews		ent sufficient to destroy pathogenic						
		( <sup>2</sup> ) and/or [in the case of dogchews made from animal by-pr treatment of at least 90 °C throughout their substant		ungulates or from fish, to a heat						
	II.3.	were examined by random sampling of at least five samples from plant and complies with the following standards ( $^3$ ):	m each processed batch taken during	or after storage at the processing						
		Salmonella: absence in 25 g: n = 5, c = 0, m = 0, M	= 0,							
		Enterobacteriaceae: $n = 5, c = 2, m = 10, M = 300$ in 1 gram	ç							
	II.4.	have undergone all precautions to avoid contamination with pat	hogenic agents after treatment;							
	II.5.	were packed in new packaging;								

П.	Health inf	formation	II.a. Certificate reference No	II.b.			
II.6.							
	( <sup>2</sup> ) either	No 999/2001 of the European Parliament and of the Council ( <sup>4</sup> ) or mechanically separated meat obtained from bones bovine, ovine or caprine animals; and the animals from which this product is derived have not been slaughtered aft stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity;]					
	( <sup>2</sup> ) or	[the product does not contain and is not derived from bovine, ovine or caprine materials other than those derived from animals born, continuously reared and slaughtered in a country or region classified as posing a negligible BSE risk by a decision in accordance with Article 5(2) of Regulation (EC) No 999/2001;]					
II.7.	in addition	as regards TSE:					
	( <sup>2</sup> ) either	[in case of animal by-products intended for feeding the ovine and caprine animals from which these pr three years on a holding where no official movemen the following requirements for the last three years:	oducts are derived have been kept co	ntinuously since birth or for the las			
		(i) it has been subject to regular official veterinary	checks;				
		<ul> <li>(ii) no classical scrapie case, as defined in point 2 following the confirmation of a classical scrapie</li> </ul>		999/2001, has been diagnosed or			
		- all animals in which classical scrapie was c	onfirmed have been killed and destroy	ved, and			
		<ul> <li>— all goats and sheep on the holding have genotype and breeding ewes carrying at learning at learning and breeding ewes carrying at learning and the sheet of the</li></ul>					
		<li>(iii) ovine and caprine animals, with the exception of only if they come from a holding which complie</li>					
	( <sup>2</sup> ) or	[in case of animal by-products intended for feeding and destined to a Member State listed in the Anne; animals from which these products are derived have where no official movement restriction is imposed du for the last seven years:	x to Commission Regulation (EC) No been kept continuously since birth or f	546/2006 ( <sup>5</sup> ), the ovine and caprin for the last seven years on a holdin			
		(i) it has been subject to regular official veterinary	checks;				
		<ul> <li>(ii) no classical scrapie case, as defined in point 2 following the confirmation of a classical scrapie</li> </ul>		999/2001, has been diagnosed of			
		- all animals in which classical scrapie was c	onfirmed have been killed and destroy	ved, and			
		<ul> <li>all goats and sheep on the holding have genotype and breeding ewes carrying at lea</li> </ul>					
		<ul> <li>(iii) ovine and caprine animals, with the exception of only if they come from a holding which complie</li> </ul>					
Notes							
Part I	:						
		I.6: Person responsible for the consignment in the Eu nay be filled in if the certificate is for import commodi		in only if it is a certificate for trans			
		.12: Place of destination: this box is to be filled in only ee zones, free warehouses and custom warehouses.	/ if it is a certificate for transit commo	lity. The products in transit can onl			

COUNTRY	1	Dogchev				
II. Health information	II.a. Certificate reference No	II.b.				
- Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in the event of unloading and reloading.						
- Box reference I.19: Alternatively, commodity codes 2309 and 4101 may be chosen.						
- Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be given.						
- Box reference I.25: technical use: any use other than for animal con	nsumption.					
- Box reference I.26 and I.27: fill in according to whether it is a trans	it or an import certificate.					
Part II:						
( <sup>1a</sup> ) OJ L 300, 14.11.2009, p. 1.						
( <sup>1b</sup> ) OJ L 54, 26.2.2011, p. 1.						
( <sup>2</sup> ) Delete as appropriate.						
( <sup>3</sup> ) Where:						
n = number of samples to be tested;						
$m$ = threshold value for the number of bacteria; the result is considering $m_{\rm c}$	dered satisfactory if the number of bact	eria in all samples does not exceed				
M = maximum value for the number of bacteria; the result is consider or more; and	dered unsatisfactory if the number of ba	acteria in one or more samples is N				
c = number of samples the bacterial count of which may be betwee count of the other samples is m or less.	een m and M, the sample still being co	onsidered acceptable if the bacteria				
( <sup>4</sup> ) OJ L 147, 31.5.2001, p. 1.						
( <sup>5</sup> ) OJ L 94, 1.4.2006, p. 28.						
- The signature and the stamp must be in a different colour to that of	f the printing.					
<ul> <li>Note for the person responsible for the consignment in the Europ accompany the consignment until it reaches the border inspection p</li> </ul>		or veterinary purposes and has to				
Official veterinarian/Official inspector						
Name (in capital letters):	Qualification	and title:				
Date:	Signature:					
Stamp:						

### [<sup>F14</sup>CHAPTER 3(D)

#### Health certificate

# for raw pet food for direct sale or animal by-products to be fed to fur animals, intended for dispatch to or for transit through (<sup>2</sup>) the European Union]

cou	NTR	(		Veterinary certificate to EU		
	l.1.	Consignor Name	I.2. Certificate reference No	l.2.a.		
		Address	I.3. Central competent authority			
		Tel.	I.4. Local competent authority			
ment	1.5.	Consignee Name	I.6. Person responsible for the lo Name	ad in EU		
nsigr		Address	Address			
dispatched consignment		Postoode Tel.	Postcode Tel.			
of dispat	1.7.	Country of origin ISO code I.8. Region of origin Code	I.9. Country of ISO code destination	I.10. Region of Code destination		
ils	l.11.	Place of origin	I.12. Place of destination			
Part I: Details		Name Approval number Address		istom warehouse 🗌 proval number		
Part		Name Approval number Address	Postcode	provar number		
		Name Approval number Address				
	I.13.	Place of loading	I.14. Date of departure			
	l.15.	Means of transport	I.16. Entry BIP in EU			
		Aeroplane Ship Railway wagon				
		Road vehicle Other I Identification	l.17.			
		Documentation references				
	l.18.	Description of commodity	I.19. Commodity co	de (HS code)		
				I.20. Quantity		
	I.21.	Temperature of product		I.22. Number of packages		
		Ambient Chilled	Frozen			
	1.23.	Seal/Container No		I.24. Type of packaging		
	1.25.	Commodities certified for:				
		Animal feedingstuff Technical u	se 🗌			
	1.26.	For transit through EU to third country	I.27. For import or admission into I			
	1.28.	Identification of the commodities				
		Species Nature of commodity Approv (Scientific name)	val number of establishments Manufacturing plant	Net weight Batch number		

COUNTRY		Raw pet food for direct sale or animal by-products to be fed to animals							
	П.	Health information	II.a. Certificate reference No	II.b.					
5		I, the undersigned official veterinarian, declare that I have read and of the Council ( <sup>fa</sup> ) and in particular Articles 10 thereof, and of Annex XIII and Chapter II of Annex XIV thereto, and certify	Commission Regulation (EU) No 142/20	011 ( <sup>1b</sup> ), and in particular Chapter II					
Part II: Certification	II.1.	consist of animal by-products that satisfy the health requirement	nts below;						
Certi	11.2.	consist of animal by-products:							
≓ t		(a) derived from meat which satisfies the relevant animal and	public health requirements laid down ir	1:					
Ps		<ul> <li>Commission Regulation (EU) No 206/2010 (<sup>3</sup>) and procountries, territories or parts thereof</li></ul>	O code in case of country or codes fo assical swine fever, African swine fever	r territories or parts thereof) which and swine vesicular disease for the					
		<ul> <li>and/or Commission Regulation (EC) No 798/2008 (<sup>4</sup>), ar countries, territories or parts thereof</li></ul>	O code in case of country or codes for	territories or parts thereof) as listed					
		— and/or Commission Regulation (EC) No 119/2009 ( <sup>5</sup> ), and provided the animals from which the meat is derived come from the thi countries, territories or parts thereof (ISO code in case of country or codes for territories or parts thereof) as listed in that Regulation which has been free from foot-and-mouth disease, rinderpest, classical swine fever, African swine fever, swin vesicular disease, Newcastle disease and avian influenza for the last 12 months and where no vaccination has taken place durin that time (only as relevant for the susceptible species);							
		(b) derived from animals that, at the slaughterhouse, have p slaughter and have shown no evidence of the diseases re susceptible; and							
		(c) derived from animals that have been handled in the slaught relevant provisions of Union legislation and have met req Council Regulation (EC) No 1099/2009; or							
		(d) in the case of feed for fur animals derived from aquatic ani down in Commission Decision 2006/766/EC ( <sup>6</sup> ), come from Annex II to that Decision;							
	II.3.1.	consist only of the following animal by-products:							
		<ul> <li>(a) carcasses and parts of animals slaughtered or, in the cas consumption in accordance with Union legislation, but are</li> </ul>							
		(b) parts of slaughtered animals, which are rejected as unfit communicable to humans or animals and derive from c legislation;							
	11.3.2.	in the case of feed for fur animals in addition to II.3.1. consist	also of the following animal by-product	is:					
		( <sup>2</sup> ) either [- animal by-products from poultry and lagomorphs No 853/2004, which did not show any signs of							
		( <sup>2</sup> ) and/or [- blood of animals which did not show any signs from animals other than ruminants that have b slaughter for human consumption following an	een slaughtered in a slaughterhouse a	fter having been considered fit for					
		( <sup>2</sup> ) and/or [- animal by-products arising from the production greaves and centrifuge or separator sludge from		mption, including degreased bone,					
		( <sup>2</sup> ) and/or [- products of animal origin, or foodstuffs containing products of animal origin, which are no longer intended for consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defe- which no risk to public or animal health arises;]							
		( <sup>2</sup> ) and/or [- pet food and feedingstuffs of animal origin, or fe longer intended for feeding for commercial rea defects from which no risk to public or animal	sons or due to problems of manufactu						
		( <sup>2</sup> ) and/or [- blood, placenta, wool, feathers, hair, horns, hor any disease communicable through that produce		animals that did not show signs of					
		( <sup>2</sup> ) and/or [- aquatic animals, and parts of such animals, exce to humans or animals;]	ept sea mammals, which did not show a	ny signs of diseases communicable					

ш

#### Status: Point in time view as at 23/02/2015. Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011. (See end of Document for details)

#### COUNTRY animals Health information II.a. Certificate reference No II.b. (²) and/or [animal by-products from aquatic animals originating from plants or establishments manufacturing products for human consumption;] [- the following material originating from animals which did not show any signs of disease communicable through that material to humans or animals: (2) and/or (i) shells from shellfish with soft tissue or flesh: (ii) the following originating from terrestrial animals: - hatchery by-products, eaas. - egg by-products, including egg shells; (iii) day-old chicks killed for commercial reasons;] (2) and/or [- animal by-products from aquatic or terrestrial invertebrates other than species pathogenic to humans or animals;] [- animals and parts thereof of the zoological orders of Rodentia and Lagomorpha, except Category 1 material as referred to in Article 8(a)(iii), (iv) and (v) of Regulation (EC) No 1069/2009 and Category 2 material as referred to in Article 9(a) to (2) and/or (g) of that Regulation; II.4. have been obtained and prepared without contact with other material not complying with the conditions laid down in the Regulation (EC) No 1069/2009, and it has been handled so as to avoid contamination with pathogenic agents; have been packed in final packaging which bear labels indicating 'RAW PET FOOD — NOT FOR HUMAN CONSUMPTION' or 'ANIMAL BY-PRODUCTS FOR FEED FOR FUR ANIMALS — NOT FOR HUMAN CONSUMPTION' and then in leak-proof and officially sealed boxes/containers or in new packaging preventing any leakage and officially sealed boxes/containers which bear labels indicating 'RAW PET FOOD — NOT FOR HUMAN CONSUMPTION' or 'ANIMAL BY-PRODUCTS FOR FEED FOR FUR ANIMALS — NOT FOR HUMAN CONSUMPTION. II.5. CONSUMPTION', and the name and the address of the establishment of destination; II.6. in the case of raw pet food: (a) have been prepared and stored in a plant approved and supervised by the competent authority in accordance with Article 24 of Regulation (EC) No 1069/2009; and (b) were examined by random sampling of at least five samples from each batch taken during storage (before dispatch) and complies with the following standards (7) Salmonella: absence in 25 g: n=5, c=0, m=0, M=0 Enterobacteriaceae: n=5, c=2, m=10, M=5000 in 1 gram; 11.7. (2) either Ithe product does not contain and is not derived from specified risk material as defined in Annex V to Regulation (EC) No [the product does not contain and is not derived from specified risk material as defined in Annex V to Hegulation (EC) No 999/2001 of the European Parliament and of the Council (<sup>8</sup>) or mechanically separated meat obtained from bones of bovine, ovine or caprine animals; and the animals from which this product is derived have not been slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity;] (2) or [the product does not contain and is not derived from bovine, ovine or caprine materials other than those derived from animals born, continuously reared and slaughtered in a country or region classified as posing a negligible BSE risk by a decision in accordance with Article 5(2) of Regulation (EC) No 999/2001;] II.8. in addition as regards TSE: [in case of animal by-products intended for feeding ruminants and containing milk or milk products of ovine or caprine origin, the ovine and caprine animals from which these products are derived have been kept continuously since birth or for the last three years on a holding where no official movement restriction is imposed due to a suspicion of TSE and which has satisfied the following requirements for the last three years: (<sup>2</sup>) either (i) it has been subject to regular official veterinary checks; (ii) no classical scrapie case, as defined in point 2(g) of Annex I to Regulation (EC) No 999/2001, has been diagnosed or, following the confirmation of a classical scrapie case: — all animals in which classical scrapie was confirmed have been killed and destroyed, and — all goats and sheep on the holding have been killed and destroyed, except for breeding rams of the ARR/ARR genotype and breeding ewes carrying at least one ARR allele and no VRQ allele;

(iii) ovine and caprine animals, with the exception of sheep of the ARR/ARR prion genotype, are introduced into the holding only if they come from a holding which complies with the requirements set out in points (i) and (ii).]

Raw pet food for direct sale or animal by-products to be fed to fur

### Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011. (See end of Document for details)

### Raw pet food for direct sale or animal by-products to be fed to fur animals

COUNTRY		animals
II.	Health inf	ormation II.a. Certificate reference No II.b.
	(²) or	[in case of animal by-products intended for feeding ruminants and containing milk or milk products of ovine or caprine origin, and destined to a Member State listed in the Annex to Commission Regulation (EC) No 546/2006 ( <sup>9</sup> ), the ovine and caprine animals from which these products are derived have been kept continuously since birth or for the last seven years on a holding where no official movement restriction is imposed due to a suspicion of TSE and which has satisfied the following requirements for the last seven years:
		(i) it has been subject to regular official veterinary checks;
		(ii) no classical scrapie case, as defined in point 2(g) of Annex I to Regulation (EC) No 999/2001, has been diagnosed or following the confirmation of a classical scrapie case:
		- all animals in which classical scrapie was confirmed have been killed and destroyed, and
		<ul> <li>all goats and sheep on the holding have been killed and destroyed, except for breeding rams of the ARR/ARF genotype and breeding ewes carrying at least one ARR allele and no VRQ allele;</li> </ul>
		(iii) ovine and caprine animals, with the exception of sheep of the ARR/ARR prion genotype, are introduced into the holding only if they come from a holding which complies with the requirements set out in points (i) and (ii).]
Notes		
Part I:	:	
		.6: Person responsible for the consignment in the European Union: this box is to be filled in only if it is a certificate for transi hay be filled in if the certificate is for import commodity.
		.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only if one warehouses and custom warehouses.
		.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship) is to be provided. In ng and reloading, the consignor must inform the BIP of entry into the EU.
— Во	x I.19: use th	ne appropriate Harmonized System (HS) code under the following heading: 05.11.
— Во	x reference I	.23: for bulk containers, the container number and the seal number (if applicable) should be given.
— Bo	x reference I	.25: technical use: any use other than for animal consumption.
— Bo	x reference I	.26 and I.27: fill in according to whether it is a transit or an import certificate.
— Bo	x reference I	.28:
Na	ture of comn	nodity: select raw pet food or animal by-product.
In e	case of raw	material for manufacture of raw pet food indicate scientific name of the species.
In ( Mo	case of raw ollusca, Crust	material for manufacture of feed for fur animals select from the following: Aves, Ruminantia, Mammalia - Ruminantia, Pesca acea, Invertebrata.
Part II	l:	
( <sup>1a</sup> ) O	J L 300, 14.	11.2009, p. 1.
( <sup>1b</sup> ) O	J L 54, 26.2	.2011, p. 1
(²) D	elete as app	ropriate.
( <sup>3</sup> ) O	J L 73, 20.3	.2010, p. 1.
( <sup>4</sup> ) O	J L 226, 23.	8.2008, p. 1.
( <sup>5</sup> ) O	J L 39, 10.2	.2009, p. 12.

cou	NTRY	Raw pet food for direct sale or ar animals	imal by-products to be fed to fu			
١١.	Health information	II.a. Certificate reference No	II.b.			
(6)	OJ L 320, 18.11.2006, p. 53.					
(7)	Where:					
	n = number of samples to be tested;					
	m = threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria in all samples does not exceed m;					
	M = maximum value for the number of bacteria; the result is considered unsatisfactory if the number of bacteria in one or more samples is M or more; and					
	c = number of samples the bacterial count of which may be betwe count of the other samples is m or less.	en m and M, the sample still being co	onsidered acceptable if the bacterial			
(8)	OJ L 147, 31.5.2001, p. 1.					
(9)	OJ L 94, 1.4.2006, p. 28.					
- ·	The signature and the stamp must be in a different colour to that of	the printing.				
	Note for the person responsible for the consignment in the Europ accompany the consignment until it reaches the border inspection po		or veterinary purposes and has to			
Offi	cial veterinarian/Official inspector					
	Name (in capital letters):	Qualifica	ation and title:			
	Date:	Signatur	e:			
:	Stamp:					

#### **Textual Amendments**

**F14** Substituted by Commission Regulation (EU) No 717/2013 of 25 July 2013 amending Regulation (EU) No 142/2011 as regards the entries for animal welfare in certain model health certificates (Text with EEA relevance).

#### CHAPTER 3(E)

### Health certificate

For flavouring innards for use in the manufacture of petfood, intended for dispatch to or for transit through  $\binom{2}{1}$  the European Union

cou	UNTRY									Veterinary certific	cate to EU
	l.1.	Consignor				1.2.	Certificat	e reference N	٩o	I.2.a.	
		Name				I.3. Central competent authority					
		Address			1.5.	Central C	competent au	anonty			
	Tel.			1.4.	Local co	mpetent auth	ority				
	1.5.	Consignee									
ent	1.5.	Name				1.6.		esponsible fo	r the load	in EU	
		Address					Name				
nsić		Address					Address				
8		Postcode					Postcode	9			
hed		Tel.					Tel.				
dispatched consignment	17	Country of origin	ISO code	I.8. Region of origin	Code	1.9.	Country	of I	SO code	I.10. Region of	Code
dist	1.7.	Country of origin	130 COUE	I.o. Region of ongin	Code	1.9.	destinatio	on	50 COUE	destination	Code
5											
I: Details	l.11.	Place of origin				I.12.	Place of	destination			
- 		Name		Approval number			Name			Custom warehouse	1
Part		Address					Address			Approval number	
"		Name Address		Approval number							
		Name		Annual number			Postcode	Э			
		Address		Approval number							
	I.13.	Place of loading				I.14. Date of departure					
	l.15.	Means of transport				I.16. Entry BIP in EU					
		Aeroplane 🔲	Ship 🗌	Railway wagon							
		Road vehicle	Other	]		1.17.					
		Identification									
		Documentation refe	erences								
	l.18.	. Description of com	modity				I.19. Commodity code (HS code)				
									1.20. Q	uantity	
	I.21.	Temperature of pro	oduct						1.22. N	umber of packages	
		Ambient		Chilled		Froze	n 🗖				
	1.23.	Seal/Container No				I.24. Type of packaging					
	1.25.	. Commodities certif	ied for:								
		Animal feedingstuff		Technical use							
	1.26.	. For transit through	EU to third	country		1.27.	For impo	rt or admissio	on into EU		
		Third country		ISO code							
	1.28.	Identification of the	commoditie	s							
		Species (Scientific name)	Natu	re of commodity	Approval nu Mar		of establis ring plant		Net	weight Batch	number

COUNTRY				Flavouring innards for use in the manufacture of petfood								
	П.	Health info	rmation	II.a. Certificate reference No	II.b.							
		I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 of the European Parlia and of the Council ( <sup>Ia</sup> ) and in particular Article 8 and 10 thereof, and Commission Regulation (EU) No 142/2011 ( <sup>Ib</sup> ), and in parti Annex XIII, Chapter III and Annex XIV, Chapter II thereof and certify that the flavouring innards products described above:										
tion	II.1.	consist of a	nimal by-products that satisfy the animal health req	uirements below;								
ertifica	11.2.	have been	prepared including the following animal by-products	which are exclusively:								
Part II: Certification		( <sup>2</sup> ) either	[- carcases and parts of animals slaughtered or, in human consumption in accordance with Union reasons;]									
		(²) and/or	[- carcases and the following parts originating eithe considered fit for slaughter for human consumption animals from game killed for human consumption	n following an ante-mortem inspection	or bodies and the following parts of							
	-	<ul> <li>(i) carcases or bodies and parts of animals which are rejected as unfit for human consumption in accordance with Unio legislation, but which did not show any signs of disease communicable to humans or animals;</li> </ul>										
			(ii) heads of poultry;									
			<ul> <li>(iii) hides and skins, including trimmings and spli metacarpus bones, tarsus and metatarsus bo</li> </ul>									
			(iv) pig bristles;									
			(v) feathers;]									
		( <sup>2</sup> ) and/or	[- blood of animals which did not show any signs of animals other than ruminants that have been slau for human consumption following an ante-morter	ightered in a slaughterhouse after havi	ng been considered fit for slaughter							
		(²) and/or	[- animal by-products arising from the production or greaves and centrifuge or separator sludge from		imption, including degreased bone,							
		(²) and/or	[- products of animal origin, or foodstuffs containin consumption for commercial reasons or due to which no risk to public or animal health arise;]									
		( <sup>2</sup> ) and/or	[- petfood and feedingstuffs of animal origin, or feed longer intended for feeding for commercial reas defects from which no risk to public or animal he	ons or due to problems of manufactu								
		( <sup>2</sup> ) and/or	[- blood, placenta, wool, feathers, hair, horns, hoof any disease communicable through that product		animals that did not show signs of							
		( <sup>2</sup> ) and/or	[- aquatic animals, and parts of such animals, except to humans or animals;]	ot sea mammals, which did not show a	ny signs of diseases communicable							
		( <sup>2</sup> ) and/or	[- animal by-products from aquatic animals origin consumption;]	ating from plants or establishments	manufacturing products for human							
		( <sup>2</sup> ) and/or	[- the following material originating from animals wh to humans or animals:	ich did not show any signs of disease	communicable through that material							
			(i) shells from shellfish with soft tissue or flesh;									

COUNTRY			Flavouring innards for use in the manufacture of			
П.	Health information		II.a. Certificate reference No	II.b.		
		(ii) the following originating from terrestrial animal	ls:			
		— hatchery by-products,				
		— eggs,				
		<ul> <li>egg by-products, including egg shells;</li> </ul>				
		(iii) day-old chicks killed for commercial reasons;]	l			
	(²) and/or	[- animal by-products from aquatic or terrestrial inve	rtebrates other than species patho	ogenic to humans or animals;]		
	(²) and/or	[- material from animals which have been treated wit the import of the material being permitted in according to the import of the material being permitted in according to the import of the material being permitted in according to the import of the material being permitted in according to the import of the material being permitted in according to the import of the material being permitted in according to the import of the material being permitted in according to the import of the material being permitted in according to the import of the material being permitted in according to the import of the material being permitted in according to the import of the material being permitted in according to the import of the material being permitted in according to the import of the material being permitted in according to the import of the material being permitted in according to the import of the material being permitted in according to the import of the material being permitted in according to the import of the material being permitted in according to the import of the material being permitted in according to the import of the material being permitted in according to the import of the material being permitted in according to the import of the import o				
II.3.	have beer agents;	n subjected to processing in accordance with Annex XI	III, Chapter III of Regulation (EU) N	lo 142/2011, in order to kill pathogen		
II.4.		n examined by the competent authority taking a rando standards ( <sup>3</sup> ):	om sample immediately prior to dis	spatch and found it to comply with th		
	Salmonella	a: absence in 25g: n = 5, c = 0, m = 0,	M = 0,			
	Enterobac	teriaceae: n = 5, c = 2, m = 10, M = 300 in 1 gr	ram;			
II.5.	the end p	roduct was:				
	( <sup>2</sup> ) either	[packed in new or sterilised bags,]				
	(²) or	[transported in bulk in containers or other means of approved by the competent authority before use,]	transport that were thoroughly clea	ned and disinfected with a disinfecta		
	and which	bear labels indicating 'NOT FOR HUMAN CONSUM	PTION';			
II.6.	the end p	roduct was stored in enclosed storage;				
II.7. II.8.	the produc	ct has undergone all precautions to avoid contamination	on with pathogenic agents after tre	patment;		
	( <sup>2</sup> ) either	[the product does not contain and is not derived fro 999/2001 of the European Parliament and of the Co ovine or caprine animals; and the animals from wh means of gas injected into the cranial cavity or killed by means of an elongated rod-shaped instrument in	uncil ( <sup>4</sup> ) or mechanically separated ich this product is derived have n by the same method or slaughtered	I meat obtained from bones of bovin ot been slaughtered after stunning b		
	( <sup>2</sup> ) or	[the product does not contain and is not derived from born, continuously reared and slaughtered in a cour accordance with Article 5(2) of Regulation (EC) No	ntry or region classified as posing			
II.9.	in addition	as regards TSE:				
	( <sup>2</sup> ) either	[in case of animal by-products intended for feeding n the ovine and caprine animals from which these pro three years on a holding where no official movement the following requirements for the last three years:	ducts are derived have been kept	continuously since birth or for the la		
		(i) it has been subject to regular official veterinary	checks;			
		<ul> <li>(ii) no classical scrapie case, as defined in point 2 following the confirmation of a classical scrapie</li> </ul>		No 999/2001, has been diagnosed o		
		- all animals in which classical scrapie was co	nfirmed have been killed and des	troyed, and		
		<ul> <li>— all goats and sheep on the holding have b genotype and breeding ewes carrying at least</li> </ul>				

cou	NTRY		Flavouring innards for use in the manufacture of petfood				
П.	Health in	formation	II.a. Certificate reference No	II.b.			
		(iii) ovine and caprine animals, with the exception of only if they come from a holding which complie					
	( <sup>2</sup> ) or	[in case of animal by-products intended for feeding and destined to a Member State listed in the Annex animals from which these products are derived have where no official movement restriction is imposed du for the last seven years:	x to Commission Regulation (EC) No been kept continuously since birth or t	546/2006 ( <sup>5</sup> ), the ovine and caprine for the last seven years on a holding			
	(i) it has been subject to regular official veterinary checks;						
		<ul> <li>(ii) no classical scrapie case, as defined in point 2 following the confirmation of a classical scrapie</li> </ul>		999/2001, has been diagnosed or,			
		- all animals in which classical scrapie was co	onfirmed have been killed and destroy	ved, and			
	<ul> <li>— all goats and sheep on the holding have been killed and destroyed, except for breeding rams of the ARR/A genotype and breeding ewes carrying at least one ARR allele and no VRQ allele;</li> </ul>						
		<li>(iii) ovine and caprine animals, with the exception c only if they come from a holding which complie</li>					
Note	es						
Part	l:						
		I.6: Person responsible for the consignment in the Eu nay be filled in if the certificate is for import commodition		in only if it is a certificate for transit			
		I.12: Place of destination: this box is to be filled in only are zones, free warehouses and custom warehouses.	y if it is a certificate for transit commo	dity. The products in transit can only			
		I.15: Registration number (railway wagons or containe event of unloading and reloading.	er and lorries), flight number (aircraft)	or name (ship); information is to be			
— E	Box reference	I.19: use the appropriate HS code: 05.04 or 05.11.91					
— E	Box reference	I.23: for bulk containers, the container number and th	e seal number (if applicable) should b	pe given.			
— E	Box reference	I.25: technical use: any use other than for animal con	sumption.				
— Е	Box reference	I.26 and I.27: fill in according to whether it is a transit	t or an import certificate.				
— E	Box reference	I.28: define the innard product.					
Part							
( <sup>1a</sup> )	OJ L 300, 14.	11.2009, p. 1.					
( <sup>1b</sup> )	OJ L 54, 26.2	.2011, p. 1.					
(?)	Delete as app	ropriate.					
(3)	Where:						
	n = number o	of samples to be tested;					
	m = threshold m;	value for the number of bacteria; the result is conside	ered satisfactory if the number of bact	eria in all samples does not exceed			
	M = maximun more; an	n value for the number of bacteria; the result is conside d	red unsatisfactory if the number of bac	teria in one or more samples is M or			
		of samples the bacterial count of which may be betwe the other samples is m or less.	en m and M, the sample still being co	onsidered acceptable if the bacterial			

COUNTRY	Flavouring innards for u	se in the manufacture of petfood					
II. Health information	II.a. Certificate reference No II.b.						
( <sup>4</sup> ) OJ L 147, 31.5.2001, p. 1.							
( <sup>5</sup> ) OJ L 94, 11.4.2006, p. 28.							
- The signature and the stamp must be in a different colour to that of	- The signature and the stamp must be in a different colour to that of the printing.						
- Note for the person responsible for the consignment in the European Union: This certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.							
Official veterinarian/Official inspector							
Name (in capital letters):	Qualification ar	nd title:					
Date:	Date: Signature:						
Stamp:							

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011. (See end of Document for details)

### [<sup>F14</sup>CHAPTER 3(F)

#### Health certificate

### for animal by-products (<sup>3</sup>) for the manufacture of pet food, intended for dispatch to or for transit through (<sup>2</sup>) the European Union]

COL	OUNTRY Veterinary certificate to EU								
	l.1.	Consignor Name	I.2. Certific	ate reference No	l.2.a.				
		Address	I.3. Central competent authority						
		Tel.	I.4. Local (	competent authority					
ment	1.5.	Consignee Name	I.6. Persor Name	responsible for the lo	oad in EU				
nsign		Address	Addres	s					
co peu		Postcode Tel.	Postco Tel.	de					
Part I: Details of dispatched consignment	1.7.	Country of origin ISO code I.8. Region of origin Code	I.9. Countr destina		I.10. Region of destination	Code			
ils of	I.11.	Place of origin	I.12. Place	of destination					
I: Deta		Name Approval number Address	Name Addres		ustom warehouse 🔲 oproval number				
Part		Name Approval number Address	Postco	de					
		Name Approval number Address							
	I.13.	Place of loading	I.14. Date o	f departure					
	l.15.	Means of transport	I.16. Entry E	BIP in EU					
		Aeroplane         Ship         Railway wagon           Road vehicle         Other							
		Identification	1.17.						
		Documentation references							
	l.18.	Description of commodity		I.19. Commodity co	de (HS code)				
					I.20. Quantity				
	I.21.	Temperature of product	I.22. Number of package			ges			
	1.00	Ambient Chilled	Frozen						
	1.23.	Seal/Container No			I.24. Type of packagin	9			
	1.25.	Commodities certified for:							
		Technical use							
	1.26.	For transit through EU to third country	I.27. For imp	ort or admission into	EU				
	1.00								
	1.28.	Identification of the commodities	ootoblickers	ha Numera of	Not wainte D	tob number			
		Species Nature of commodity Approval number of (Scientific name) Manufacturin		ts Number of packages	Net weight Ba	atch number			

ou	NTRY		Animal by-products for the manufacture of pet foo			
	П.	Health information	II.a. Certificate reference No II.b.			
			we read and understood Regulation (EC) No 1069/2009 of the European lation (EU) No 142/2011 ( <sup>1b</sup> ), and in particular Annex XIV, Chapter II thereof,			
5	II.1.1.	consist of animal by-products that satisfy the animal health requirements below;				
tificati	II.1.2.	have been obtained in the territory of:	( <sup>1c</sup> ) from animals:			
Part II: Certification		( <sup>2</sup> ) either [(a) that have remained in this territory since	birth or for at least the last three months before slaughter;]			
Part		( <sup>2</sup> ) or [(b) killed in the wild in this territory ( <sup>1d</sup> );]				
	II.1.3.	have been obtained from animals:				
		( <sup>2</sup> ) <i>either</i> [(a) coming from holdings:				
		rinderpest, swine vesicular disease,	which the animals are susceptible, there has been neither case/outbreak of Newcastle disease or highly pathogenic avian influenza during the prior 30 ne fever during the prior 40 days; nor in the holdings situated in their vicinity avis; and			
			/outbreak of foot-and-mouth disease during the prior 60 days, nor in the hin 25 km, during the prior 30 days; and			
		(b) which:				
		(i) were not killed to eradicate any epi	zootic disease;			
			rigin for at least 40 days before departure and which have been transported out contact with other animals which did not comply with the same health			
			the ante-mortem health inspection during the 24 hours before the slaughter re diseases referred to above for which the animals are susceptible; and			
			house before and at the time of slaughter or killing in accordance with the tion and have met requirements at least equivalent to those laid down in ation (EC) No 1099/2009;			
		( <sup>2</sup> ) or [(a) captured and killed in the wild in an are	a:			
		susceptible: foot-and-mouth disease	n no case/outbreak of any of the following diseases for which the animals are , rinderpest, Newcastle disease or highly pathogenic avian influenza during r African swine fever during the prior 40 days; and			
			eeds 20 km from the borders separating another territory of a country or part hese dates for exporting this material to the European Union; and			
		<ul> <li>(b) which after killing were transported within to a game establishment, or directly to</li> </ul>	12 hours for chilling either to a collection centre and immediately afterwards a game establishment;]			
	II.1.4.	referred to in point II.1.3 for which the animals are sus	, within a radius of 10 km, there has been no case/outbreak of diseases ceptible during the prior 30 days or, in the event of a case of disease, the ean Union has been authorised only after removal of all meat, and the total e control of an official veterinarian;			
	ll.1.5.	have been obtained and prepared without contact with been handled so as to avoid contamination with pathog	other material not complying with the conditions required above, and it has enic agents;			
	II.1.6.		akage and in officially sealed containers bearing the label indicating 'RAW FOOD' and the name and address of the EU establishment of destination;			
	II.1.7.	consist only of the following animal by-products:				
			red or, in the case of game, bodies or parts of animals killed, and which are e with Union legislation, but are not intended for human consumption for			

Ι.	Health information	Animal by-products for the manufacture of pet for II.a. Certificate reference No II.b.
	( <sup>2</sup> ) and/or [-	carcasses and the following parts originating either from animals that have been slaughtered in a slaughterhouse and were considered fit for slaughter for human consumption following an ante-mortem inspection or bodies and the following parts of animals from game killed for human consumption in accordance with Union legislation:
		<ul> <li>(i) carcasses or bodies and parts of animals which are rejected as unfit for human consumption in accordance with Union legislation, but which did not show any signs of disease communicable to humans or animals;</li> </ul>
		(ii) heads of poultry;
		<ul> <li>(iii) hides and skins, including trimmings and splitting thereof, horns and feet, including the phalanges and the carpu and metacarpus bones, tarsus and metatarsus bones, of animals other than ruminants;</li> </ul>
		(iv) pig bristles;
		(v) feathers;]
	( <sup>2</sup> ) and/or [-	animal by-products arising from the production of products intended for human consumption, including degrease bone, greaves and centrifuge or separator sludge from milk processing;]
	( <sup>2</sup> ) and/or [-	products of animal origin, or foodstuffs containing products of animal origin, which are no longer intended for huma consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects fror which no risk to public or animal health arise;]
	( <sup>2</sup> ) and/or [-	aquatic animals, and parts of such animals, except sea mammals, which did not show any signs of disease communicable to humans or animals;]
	( <sup>2</sup> ) and/or [-	animal by-products from aquatic animals originating from plants or establishments manufacturing products for huma consumption;]
	( <sup>2</sup> ) and/or [-	the following material originating from animals which did not show any signs of disease communicable through th material to humans or animals:
		(i) shells from shellfish with soft tissue or flesh;
		(ii) the following originating from terrestrial animals:
		— hatchery by-products,
		— eggs,
		<ul> <li>egg by-products, including egg shells;</li> </ul>
		(iii) day-old chicks killed for commercial reasons;]
	( <sup>2</sup> ) and/or [-	animal by-products from aquatic or terrestrial invertebrates, other than species pathogenic to humans or animals
	( <sup>2</sup> ) and/or [-	material from animals which have been treated with certain substances which are prohibited pursuant to Directiv 96/22/EC, the import of the material being permitted in accordance with Article 35(a)(ii) of Regulation (EC) N 1069/2009;]
.1.8.		ep-frozen at the plant of origin or have been preserved in accordance with EU legislation in such a way that they w een dispatch and delivery to the plant of destination;
.1.9.		raw material derived from animals which have been treated with certain substances prohibited in accordance wit 2/EC for the manufacture of pet food, the import being permitted in accordance with Article 35(a)(ii) of Regulation (EC :
	carbon on separate c	n marked in the third country before entry into the territory of the Union by a cross of liquefied charcoal or activate each outer side of each frozen block, or, when the raw material is transported in pallets which are not divided in onsignments during transport to the pet food plant of destination, on each outer side of each pallet, in a way that th overs at least 70 % of the diagonal length of the frozen block and be of at least 10 cm width;

COUNTRY			Animal by-products for the manufacture of pet food		
II. Hea	Ith informa	tion	II.a. Certificate reference No	II.b.	
	Union	e of material which is not frozen, the raw materia by spraying it with liquefied charcoal or by app al; and			
		case the animal by-products are made up of ra d raw material, all the raw materials have been			
( <sup>2</sup> ) ( <sup>4</sup> ) [II.2.	Specific r	requirements			
( <sup>2</sup> ) ( <sup>5</sup> ) II.2.1.		oducts in this consignment come from anima n programmes against foot-and-mouth disease mals.			
( <sup>2</sup> ) ( <sup>6</sup> ) II.2.2.	maturated	oducts in this consignment consist only of animal at an ambient temperature of more than + 2 $^\circ$ nd deboned meat of domestic animals, for at le	C for at least three hours, or in the ca		
II.3.					
	(²) either	[the product does not contain and is not derive 999/2001 of the European Parliament and of bovine, ovine or caprine animals; and the an stunning by means of gas injected into the or central nervous tissue by means of an elonge	the Council ( <sup>7</sup> ) or mechanically separ- imals from which this product is derive ranial cavity or killed by the same meth	rated meat obtained from bones of ad have not been slaughtered after hod or slaughtered by laceration of	
	(²) or	[the product does not contain and is not deriv animals born, continuously reared and slaught decision in accordance with Article 5(2) of Re	tered in a country or region classified a		
II.4.	in addition	as regards TSE:			
	( <sup>2</sup> ) either	[in case of animal by-products intended for fe origin, the ovine and caprine animals from wh for the last three years on a holding where n which has satisfied the following requirement	ich these products are derived have be o official movement restriction is impos	een kept continuously since birth o	
		(i) it has been subject to regular official veter	inary checks;		
		<ul> <li>(ii) no classical scrapie case, as defined in po or, following the confirmation of a classical</li> </ul>		No 999/2001, has been diagnosed	
		- all animals in which classical scrapie w	vas confirmed have been killed and de	estroyed, and	
		<ul> <li>all goats and sheep on the holding has genotype and breeding ewes carrying</li> </ul>			
		(iii) ovine and caprine animals, with the exce holding only if they come from a holding v			
	(²) or	[in case of animal by-products intended for fee origin, and destined to a Member State listed in caprine animals from which these products are on a holding where no official movement restr following requirements for the last seven years	the Annex to Commission Regulation ( derived have been kept continuously si iction is imposed due to a suspicion of	EC) No 546/2006 ( <sup>8</sup> ), the ovine and ince birth or for the last seven year	
		(i) it has been subject to regular official veter	nary checks;		
		<li>(ii) no classical scrapie case, as defined in poir following the confirmation of a classical scr</li>		999/2001, has been diagnosed o	
		- all animals in which classical scrapie w	as confirmed have been killed and de	stroyed, and	
		<ul> <li>— all goats and sheep on the holding hav genotype and breeding ewes carrying a</li> </ul>			
		<li>(iii) ovine and caprine animals, with the except holding only if they come from a holding w</li>			

COUNTRY	Animal by-products	s for the manufacture of pet food			
II. Health information	II.a. Certificate reference No	II.b.			
Notes					
Part I:					
Box reference I.6: Person responsible for the consignment in the European Union: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.					
<ul> <li>Box reference I.12: Place of destination: this box is to be filled in only be stored in free zones, free warehouses and custom warehouses.</li> </ul>	/ if it is a certificate for transit commod	ity. The products in transit can only			
<ul> <li>Box reference I.15: Registration number (railway wagons or containe provided in case of unloading and reloading.</li> </ul>	er and lorries), flight number (aircraft) o	or name (ship); information is to be			
- Box reference I.19: use the appropriate HS code: 05.11.91 or 05.11	.99.				
- Box reference I.23: for bulk containers, the container number and the	e seal number (if applicable) should b	e included.			
- Box reference I.25: technical use: any use other than for animal cor	sumption.				
- Box reference I.26 and I.27: fill in according to whether it is a transi	t or an import certificate.				
- Box reference I.28: Manufacturing plant: provide the veterinary contr	ol number of the approved establishm	ent.			
Part II:					
( <sup>1a</sup> ) OJ L 300, 14.11.2009, p. 1.					
( <sup>1b</sup> ) OJ L 54, 26.2.2011, p. 1.					
(1c) The name and ISO code number of the exporting country as laid of	lown in:				
- Part 1 of Annex II to Regulation (EU) No 206/2010,					
- the Annex to Regulation (EC) No 798/2008, and					
- the Annex to Regulation (EC) No 119/2009.					
In addition the ISO code of territories and parts thereof referred susceptible species concerned) should be included.	to in Regulations mentioned in this	footnote (where applicable for the			
( <sup>1d</sup> ) Only for countries from where game meat intended for human cons European Union.	umption of the same animal species is	s authorised for importation into the			
( <sup>2</sup> ) Delete as appropriate.					
( <sup>3</sup> ) Excluding raw blood, raw milk, hides and skins, hooves and horn, p these products).	ig bristles and feathers (see relevant s	specific certificates for the import of			
(4) Supplementary guarantees to be provided when the material of do African country or part thereof from where only maturated and debo for exportation to the European Union. The whole masseter muscles I, Part B(1) of Regulation (EC) No 854/2004 of the European Parliar	ned fresh meat of domestic ruminants f of bovine animals, incised in accordance	or human consumption is permitted ce with Annex I, Section IV, Chapter			
( <sup>5</sup> ) Only for certain South American countries.					
$(^{6})$ Only for certain South American and South African countries.					
( <sup>7</sup> ) OJ L 147, 31.5.2001, p. 1.					
( <sup>8</sup> ) OJ L 94, 1.4.2006, p. 28.					

COUNTRY	Animal by-products for the manufacture of pet food		
II. Health information	II.a. Certificate reference No	II.b.	
- The signature and the stamp must be in a different colour to that of	the printing.		
<ul> <li>Note for the person responsible for the consignment in the European I the consignment until it reaches the border inspection post.</li> </ul>	Jnion: this certificate is only for veterina	ry purposes and has to accompany	
Official veterinarian/Official inspector			
Name (in capital letters):	Qualificat	tion and title:	
Date:	Signature	ə:	
Stamp:			

### [<sup>F1</sup>CHAPTER 4(A)

#### Health certificate

For the import of blood and blood products from equidae to be used outside the feed chain, for dispatch to or for transit through  $(^2)$  the European Union]

COUNTRY Veterin					
	l.1.	Consignor Name	I.2. Certificate reference No I.2.a.		
		Address	I.3. Central competent authority		
		Tel.	I.4. Local competent authority		
nent	1.5.	Consignee	I.6. Person responsible for the load in EU		
lignn		Name Address	Name Address		
cons		Postcode	Postcode		
hed		Tel.	Tel.		
Part I: Details of dispatched consignment	1.7.	Country of origin ISO code I.8. Region of origin Code	I.9. Country of ISO code I.10. Region of Code destination		
ls of	1 1 1	Place of origin	I.12. Place of destination		
Detai		Name Approval number	Name Custom warehouse		
1		Address	Address Approval number		
Pai		Name Approval number Address	Postcode		
		Name Approval number Address			
	I.13.	Place of loading	I.14. Date of departure		
	I.15.	Means of transport	I.16. Entry BIP in EU		
		Aeroplane 🗋 Ship 🗋 Railway wagon 🗋			
		Road vehicle Other	1.17.		
		Identification Documentation references			
	1.18.	Description of commodity	I.19. Commodity code (HS code)		
			I.20. Quantity		
	1.21.	Temperature of product	I.22. Number of packages		
		Ambient Chilled	Frozen		
	1.23.	Seal/Container No	I.24. Type of packaging		
	1.25.	Commodities certified for:			
		Technical use			
	1.26.	For transit through EU to third country	I.27. For import or admission into EU		
		Third country ISO code			
	1.28.	Identification of the commodities			
		Species (Scientific name)	Approval number of establishments Manufacturing plant		

со	UNTRY			Blood and blood products from e feed chain	quidae for purposes outside the			
П.		Health inform	nation	II.a. Certificate reference No	II.b.			
		and of the Co	gned official veterinarian, declare that I have read a uncil ( <sup>1a</sup> ) and in particular Article 8(c) and (d) and <i>J</i> Chapter IV of Annex XIII thereto, and certify that th	Article 10 thereof, and Commission Reg	gulation (EU) No 142/2011 (1b), and			
tion	II.1.	consist of blood or blood products from equidae that satisfy the health requirements below;						
ertifica	II.2.	consist exclu	sively of blood or blood products of equidae not in	ntended for human or animal consump	tion;			
Part II: Certification	II.3.	II.3. have been obtained from animals that originate from the EU Member States or from a third country, territory or part there column "third countries' lists" of row No 3 of Table 2 in Section 1 of Chapter II of Annex XIV to Regulation (EU) No 142/2 following diseases are compulsorily notifiable: African horse sickness, dourine, glanders ( <i>Burkholderia mallei</i> ), equine encept types including Venezuelan equine encephalomyelitis), equine infectious anaemia, vesicular stomatitis, rabies, anthrax;						
	II.4.	accordance v supervised by of the country	have been derived from blood from equidae, which was collected under the supervision of a veterinarian in slaughterhouses approved in accordance with Regulation (EC) No 853/2004 of the European Parliament and of the Council ( <sup>3</sup> ), in slaughterhouses approved and supervised by the competent authority of the country of collection and in facilities approved and supervised by the competent authority of the country of collection for the purpose of collecting blood from equidae for the production of blood products for purposes other than feeding for farmed animals;					
	II.5.	have been de	erived from blood which was collected from equida	ae:				
	II.5.1.	I to Council I	which on inspection on the date of blood collection did not show clinical signs of any of the compulsorily notifiable diseases listed in Annex I to Council Directive 2009/156/EC (*), and of equine influenza, equine piroplasmosis, equine rhinopneumonitis and equine viral arteritis listed in point 4 of Article 1.2.3 of the Terrestrial Animal Health Code of the World Organisation for Animal Health (OIE), 2010 edition;					
	II.5.2.		een kept for at least 30 days prior to the date of a ject to a prohibition order pursuant to Article 4(5) 9/156/EC;					
	II.5.3.		contact with equidae from a holding which was s ive 2009/156/EC;	subject to a prohibition order for animal	I health reasons pursuant to Article			
	II.5.4.	for which the	period for the prohibition order referred to in poin	ts II.5.2. and II.5.3 has been determine	ed as follows:			
		(²) either	[not all the animals of species susceptible to the period of prohibition must be at least:	disease located on the holding have be	een slaughtered , in which case the			
			<ul> <li>— six months in the case of glanders (Burkhold disease are slaughtered,</li> </ul>	<i>eria mallei</i> ), beginning on the date on v	which the equidae infected with the			
			<ul> <li>six months in the case of equine encepha beginning on the date on which the equidae</li> </ul>					
			<ul> <li>in the case of equine infectious anaemia, until remaining animals have shown a negative re</li> </ul>					
			— six months from the date of the last recorded	d case of vesicular stomatitis,				
		- one month from the date of the last recorded case of rabies,						
			- 15 days from the date of the last recorded c	case of anthrax;]				
		( <sup>2</sup> ) or [all the animals of species susceptible to the disease located on the holding have been slaughtered and the premis disinfected, in which case the period of prohibition must be 30 days, beginning on the date on which the anima slaughtered and the premises disinfected, except in the case of anthrax, where the period of prohibition shall be 1						
	II.6.		ts come from an establishment or plant approved tions set out in Article 23 or 24 of Regulation (EC		ity of the third country meeting the			
	II.7.	blood produc	ts have been produced from blood which fulfils the	e conditions referred in II.4 and II.5 an	d			
		(²) either	[has been collected from equidae which have b three months old, prior to the date of collection of during that period and the period of blood collect	on holdings under veterinary supervisio				
		(a) African horse sickness for two years;						

### Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011. (See end of Document for details)

### Blood and blood products from equidae for purposes outside the feed chain

COUNT	RY			Blood and blood products from e feed chain	quidae for purposes outside the
II.	Health info	rmation		II.a. Certificate reference No	II.b.
		(b) Venezuelar	n equine encephalomyelitis for a pe	eriod of at least two years;	
		(c) glanders			
		( <sup>2</sup> ) either	[for a period of three years;]		
		( <sup>2</sup> ) or	slaughterhouse referred to in II.4,	a the animals have passed the post-m , including a careful examination of mu s and their ramifications, after splitting	cous membranes from the trachea,
		(d) in the case	of blood products other than seru	m and plasma, vesicular stomatitis fo	r six months;]]
	(²) or	possible causa	tive pathogens for African horse sic	ng treatments, followed by an effectiv kness, equine encephalomyelitis of all sicular stomatitis and glanders ( <i>Burkho</i>	types including Venezuelan equine
		( <sup>2</sup> ) either	[heat treatment at a temperature	of 65°C for at least three hours;]	
		(²) and/or	[irradiation at 25 kGy by gamma	rays;]	
		(²) and/or	[change in pH to pH 5 for two h	ours;]	
		(²) and/or	[heat treatment of at least 80°C	throughout their substance;]]	
II.8.	all precautio and packag		en to avoid contamination of the blo	od and blood products with pathogenic	c agents during production, handling
II.9.		blood products FION" and bearing		eable containers clearly labelled "f	NOT FOR HUMAN OR ANIMAL
	(a) in the ca	ase of blood, the	approval number of the establishm	nent of collection;	
	(b) in the ca	ase of blood prod	lucts, the approval number of the e	establishment of production;	
II.10.	the products	were stored in e	enclosed storage.		
Notes					
Part I:					
			ible for the consignment in the Europe certificate is for import commodi	ropean Union: this box is to be filled i ty.	in only if it is a certificate for transit
	k reference I.1 hority.	1 and I.12: Appro	oval number: the registration numbe	er of the establishment or plant, which	has been issued by the competent
			nation: this box is to be filled in only phouses and custom warehouses.	r if it is a certificate for transit commod	lity. The products in transit can only
			umber (railway wagons or containe the consignor must inform the BIP	r and lorries), flight number (aircraft) o of entry into the EU.	or name (ship) is to be provided. Ir
— Box	( I.19: use the	appropriate Har	monized System (HS) code under	the following heading: 30.02.	
— Box	c reference 1.2	3: for bulk contai	iners, the container number and the	e seal number (if applicable) must be	included.
— Box	c reference 1.2	5: technical use:	any use other than for animal con-	sumption.	
— Box	c reference 1.2	6 and I.27: fill in	according to whether it is a transit	or an import certificate.	
— Box	c reference 1.2	28:			
(a)	Manufacturing	g plant:			
	(i) in the cas	e of blood, provi	de the approval number of the regi	istered establishment of collection;	
	(ii) in the cas	e of blood produ	cts, provide the approval number of	of the establishment of production;	
(b)	Species: sele	ct amongst the fe	ollowing: Equus cabalus, Equus as	inus, Equus cabalus*asinus.	

COUN	ITRY	Blood and blood products fi feed chain	rom equidae for purposes outside the	
П.	Health information	II.a. Certificate reference No	II.b.	
Part	11:			
( <sup>1a</sup> )	OJ L 300, 14.11.2009, p. 1.			
( <sup>1b</sup> )	OJ L 54, 26.2.2011, p. 1			
(²)	Delete as appropriate.			
( <sup>3</sup> )	OJ L 139, 30.4.2004, p. 55.			
(4)	OJ L 192, 23.7.2010, p. 1.			
_ т	- The signature and the stamp must be in a different colour to that of the printing.			
	— Note for the person responsible for the consignment in the European Union: this certificate is only for veterinary purposes and must accompan the consignment until it reaches the border inspection post.			
Offic	ial veterinarian/Official inspector			
N	lame (in capital letters):	Qu	ualification and title:	
	Date:	Sig	gnature:	
s	itamp:			

### [<sup>F3</sup>CHAPTER 4(B)

### Health certificate

# For blood products not intended for human consumption that could be used as feed material, intended for dispatch to or for transit through (<sup>2</sup>) the European Union]

JNTRY:		Veterinary certi	ficate to E
I.1.	Consignor	I.2. Certificate reference No I.2.a.	
	Name	I.3. Central competent authority	
	Address	I.4. Local competent authority	
	Tel.		
1.5.	Consignee	I.6. Person responsible for the load in EU	
	Name	Name	
	Address	Address	
	Postcode	Postcode	
	Tel.	Tel.	
I.7.	Country of ISO code I.8. Region of Code origin	I.9. Country of destination ISO code I.10. Region of destination	Code
l.11.	Place of origin	I.12. Place of destination	
	News.	Queter sector (	-
	Name Approval number Address	Custom warehouse D Name Approval number	
	Name Approval number	Address	
	Address		
	Name Approval number	Postcode	
	Address		
I.13.	Place of loading	I.14. Date of departure	
I.15.	Means of transport	I.16. Entry BIP in EU	
	Aeroplane 🛛 Ship 🗖 Railway wagon 🗖		
	Road vehicle Other	1.17.	
	Identification		
	Documentation references		
I.18.	Description of commodity	I.19. Commodity code (HS cod	le)
		I.20. Quantity	
I.21.	Temperature of product Ambient Chilled	I.22. Number of	packages
1.23.	Seal/Container No	I.24. Type of pa	ckaging
1.25.	Commodities certified for:	I	
	Animal feedingstuff  Tee	nnical use 🗖	

1.26.	. For transit through EU to third country		1.27.	For import or admission into EU	
	Third country	ISO code			
1.28.	Identification of the commoditi	es			
		Approval number	of esta	blishments	
	Species (Scientific name)	Nature of commodity		Manufacturing plant	Batch number

COUNTR	RY			Blood products	that could be used as feed mater				
II.	Health information	on	II.a.	Certificate reference No	II.b.				
I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2 the European Parliament and of the Council ( <sup>1a</sup> ) and Commission Regulation (EU) No 142/2011 ( <sup>1b</sup> ) and cer the blood products described above:									
II.1.	consist of blood products that satisfy the health requirements below;								
II.2.	consist exclusively of blood products not intended for human consumption;								
II.3.		have been prepared and stored in a plant, approved, validated and supervised by the competent authority in accordance with Article 24 of Regulation (EC) No 1069/2009;							
11.4.	have been prepared exclusively with the following animal by-products:								
	( <sup>2</sup> ) either	onsumption in accordance with Unio commercial reasons;]							
	( <sup>2</sup> ) and/or	with Union leg animals, deriv	islation ed fro for hu	d animals, which is rejected as unfit f n, but which did not show any signs of m carcases that have been slaugh man consumption following an ante-	diseases communicable to humans of tered in a slaughterhouse and wer				
11.5.	in order to inac	tivate pathogenic a	agents	, have been submitted					
	( <sup>2</sup> ) <i>either</i> [to processing in accordance with processing method								
	( <sup>2</sup> ) or			arameters which ensure that the prop pter I of Annex X to Regulation (EU) N					
	( <sup>2</sup> ) or	[in the case of blood products, including spray dried blood and blood plasma, of porcine origin intended for the feeding of porcine animals, to a heat treatment at a temperature of at least 80 °C throughout the substance and the dry blood and blood plasma is of not more than 8 % moisture with a water activity (Aw) of less than 0,60.]							
II.6.				sibility of the competent authority taking the following standards <sup>(4)</sup> :	ng a random sample immediately pric				
	Salmonella:	absence	in 25g	g: n = 5, c = 0, m = 0, M = 0,					
	Enterobacteriad	ceae: n = 5, c =	= 2, m	= 10, M = 300 in 1 gram;					
11.7.	the end produc	t was:							
	( <sup>2</sup> ) either	[packed in new	v or ste	erilised bags;]					
	( <sup>2</sup> ) or			in containers or other means of trans infectant approved by the competent					
	and which bear labels indicating 'NOT FOR HUMAN CONSUMPTION';								
II.8.	the end produc	t was stored in en	closed	storage;					
II.9.	the product has	s undergone all pre	ecautio	ons to avoid contamination with pathog	genic agents after treatment;				
	( <sup>2</sup> ) and	intended for th	e feed	d products, including spray dried bloo ding of porcine animals, has been stor r at least 6 weeks.]					
II.10.	does not contai	in and is not derive	ed from	n:					
	( <sup>2</sup> ) either	caprine anima or region class of Regulation from which thi stunning by n slaughtered b	ls and, sified a (EC) N s anim neans y lace	al or mechanically separated meat of , except for animals born, continuous is posing a negligible BSE risk by a d lo 999/2001 of the European Parliam al by-product or derived product is de of gas injected into the cranial cav ration of central nervous tissue by d into the cranial cavity.]	ly reared and slaughtered in a countri- lecision in accordance with Article 5( ent and of the Council ( <sup>5</sup> ), the animal rived, have not been slaughtered after vity or killed by the same method of				
	( <sup>2</sup> ) or	[bovine, ovine reared and sla	and c aughte	caprine materials other than those de red in a country or region classified ce with Article 5(2) of Regulation (EC)	as posing a negligible BSE risk by				

COUNTRY			Blood products not intended for human consumption tha could be used as feed materia				
II.	II. Health information			Certificate reference No		II.b.	
Note	s						
Part	l:						
-		Box reference I.6: Person responsible for the consignment in the European Union: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.					
-				box is to be filled in only if it is ones, free warehouses and custor		rtificate for transit commodity. The shouses.	
_		erence I.15: Registration numb tion is to be provided in case o			es), flig	ht number (aircraft) or name (ship);	
_	Box refe	erence I.19: use the appropriat	te HS co	de: 05.11.91 or 05.11.99.			
_	Box refe	erence I.23: for bulk containers	s, the co	ntainer number and the seal numb	ber (if a	applicable) should be included.	
-	Box refe	erence I.25: technical use: any	use oth	er than for animal consumption.			
-	Box refe	erence I.26 and I.27: fill in acco	ording to	whether it is a transit or an impor	rt certifi	icate.	
-		erence I.28: Species: select , Reptilia.	from the	following: Aves, Ruminantia, Su	uidae,	Mammalia other than Ruminantia,	
Part	II:						
( <sup>1a</sup> )	OJ L 30	0, 14.11.2009, p. 1.					
( <sup>1b</sup> )	OJ L 54	, 26.2.2011, p. 1.					
( <sup>2</sup> )	Delete a	as appropriate.					
( <sup>3</sup> )	Insert m	ethod 1 to 5 or 7 as applicable	Ð.				
(4)	Where:						
	n =	number of samples to be tes	sted;				
	m =	threshold value for the num samples does not exceed m	ber of bacteria; the result is considered satisfactory if the number of bacteria in a ;				
	M =	maximum value for the num one or more samples is M or			unsatis	factory if the number of bacteria in	
	с =			unt of which may be between m e other samples is m or less.	and M	l, the sample still being considered	
( <sup>5</sup> )	OJ L 14	7, 31.5.2001, p. 1.					
-	The sig	nature and the stamp must be	in a diffe	erent colour to that of the printing.			
-	Note for the person responsible for the consignment in the European Union: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.						
Offici	al veterin	arian					
	Na	me (in capital letters):			Qualific	cation and title:	
	Da	te:			Signati	ure:	
	Sta	imp:					
1							

# [<sup>F1</sup>CHAPTER 4(C)

### Health certificate

For untreated blood products, excluding of equidae, for the manufacture of derived products for purposes outside the feed chain for farmed animals, intended for dispatch to or for transit through (<sup>2</sup>) the European Union]

COUNTRY Veterinary certificate to EL									
	l.1.	Consignor Name		1.2. (	Certificate	e refere	ence No	l.2.a.	
		Address Tel.			I.3. Central competent authority				
					Local con	npetent	t authority		
Part I: Details of dispatched consignment	1.5.	Consignee Name Address Postcode Tel.		T J F	Person re Name Address Postcode Tel.		ble for the loa	ad in EU	
f dispatcl	1.7.	Country of origin ISO code I.8. Region of origin Co	de		Country o destinatio		ISO code	I.10. Region of destination	Code
ils o	I.11.	Place of origin		I.12. F	Place of (	destina	tion		
l: Deta		Name Approval number Address			Name Address			stom warehouse [ proval number	ו נ
Part		Name Approval number Address		F	Postcode			, <b>,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,</b>	
		Name Approval number Address							
	I.13.	Place of loading		l.14. [	Date of d	epartur	re		
	l.15.	Means of transport		I.16. E	Entry BIP	in EU			
		Aeroplane Ship Railway wagor Road vehicle Other							
		Identification Documentation references		l.17.					
	l.18.	Description of commodity			1	.19. C	ommodity cod	le (HS code)	
								I.20. Quantity	
	I.21.	Temperature of product Ambient Chilled			F	rozen		I.22. Number of p	ackages
	1.23.	Seal/Container No						I.24. Type of pack	aging
	1.25.	Commodities certified for: Technical use							
	1.26.	For transit through EU to third country		l.27. F	or import	or adr	mission into E	U	
	1.28.	Identification of the commodities							
		Species Approval (Scientific name) M		er of est sturing p		ents			Batch number

co	UNTRY				derived products for p	ding of equidae, for the manu- ourposes outside the feed chain				
	II. I	Health informat	ion	II.a. Certific	ate reference No	II.b.				
		Parliament an		read and understood Regulation (EC) No 1069/2009 of the European 8(c) and (d) and Article 10 thereof, and Commission Regulation (EU) No f, and certify that:						
ıtion	II.1.	the blood products described above consist of blood products that satisfy the health requirements below;								
ertifica	11.2.	they consist exclusively of blood products not intended for human or animal consumption;								
Part II: Certification	II.3.		hey have been prepared and stored in a plant supervised by the competent authority or in the establishment of collection, exclusively vith the following animal by-products:							
<b>a</b>		( <sup>2</sup> ) either [-	blood of slaughtered animals, which is fit for hu for human consumption for commercial reason		tion in accordance with U	Jnion legislation, but is not intended				
	-	( <sup>2</sup> ) and/or [-	blood of slaughtered animals, which is rejected which did not show any signs of diseases con slaughtered in a slaughterhouse and were con accordance with Union legislation;]	nmunicable to	humans or animals, der	ived from carcases that have been				
		( <sup>2</sup> ) and/or [-	blood of slaughtered animals, which did not sh from animals that have been slaughtered in a following an ante-mortem inspection in accord	slaughterhou	se after having been cor					
		( <sup>2</sup> ) and/or [-	blood and blood products derived from the pro-	oduction of pr	oducts intended for hum	an consumption;]				
		( <sup>2</sup> ) and/or [-	blood and blood products originating from live a product to humans or animals;]	animals that d	d not show signs of any	disease communicable through that				
		( <sup>2</sup> ) and/or [-	animal by-products derived from animals which Directive 96/22/EC or Article 2(b) of Directive		submitted to illegal treatn	nent as defined in Article 1(2)(d) of				
		( <sup>2</sup> ) and/or [-	animal by-products containing residues of oth Annex I to Directive 96/23/EC, if such residu absence thereof, in national legislation;]							
	II.4.	legislation, in		is been collected in slaughterhouses approved in accordance with Union y the competent authority of the country of collection or from live animals hority of the country of collection.						
	( <sup>2</sup> ) [II.5.		blood products derived from animals belonging re products come:	ng to the taxa Artiodactyla, Perissodactyla and Proboscidea, including their						
	II.5.1.		y where no case of rinderpest, peste des petits tion has not been carried out against those dis			een recorded for 12 months and in				
	( <sup>2</sup> ) [II.5.2.	either	(from the third countries, territories or parts th tories or parts thereof) ( <sup>3</sup> ) where no case of vaccination has not been carried out against t	foot-and-mout	h disease has been rec					
		or	[from the countries, territories or parts thereof parts thereof) ( <sup>3</sup> ) where no case of foot-and-m programmes against foot-and-mouth disease a for at least 12 months ( <sup>4</sup> );]]	outh disease	has been recorded for 1	2 months and in which vaccination				
	$(^2)$ [II.5.3. In addition, in case of animals other than Suidae and Tayass									
		( <sup>2</sup> ) either	[in the country or region of origin no case seropositive animals) has been recorded for those diseases for at least 12 months;]							
		(²) or	[in the country or region of origin vesicular sto	omatitis and b	luetongue ( <sup>2</sup> ) seropositive	e animals are present (4);]]				
	( <sup>2</sup> ) [II.5.4.	In addition, in	case of Suidae and Tayassuidae:							
	II.5.4.1.		or region of origin no case of swine vesicular dis onths and vaccination has not been carried out							

COUNT	ſRY				luding of equidae, for the manu- r purposes outside the feed chair
II.	Heal	th informati	on	II.a. Certificate reference No	II.b.
( <sup>2</sup> ) [II.5	5.4.2.	either	[in the country or region of origin no case o been recorded for 12 months and in which months;]		
(²) [II.5	5.4.2.	or	[in the country or region of origin vesicular	stomatitis seropositive animals are p	resent ( <sup>4</sup> );]
(²) [II.6	ð.		of blood products derived from poultry or othe region with code	r avian species the animals and the p	products come from the territory of the
		which has b of the OIE,	been free from Newcastle disease and highly p	athogenic avian influenza as defined	in the Terrestrial Animal Health Code
		which for a	t least 12 months has not carried out vaccinal	tion against avian influenza,	
			nimals from which the products derive have no e disease master strain showing a higher path		
II.7.		the product	s were:		
		(²) either	[packed in new or sterilised bags or bottles	.]	
		(²) or	[transported in bulk in containers or other disinfectant approved by the competent aut		ughly cleaned and disinfected with a
		the outer pa	ackaging or containers bear labels indicating '	NOT FOR HUMAN OR ANIMAL CO	DNSUMPTION";
II.8.		the product	s were stored in enclosed storage;		
11.9.		all precautio	ons were taken to avoid contamination of the	products with pathogenic agents dur	ring transport;
II.10.					
		(²) either	[the product does not contain and is not der No 999/2001 of the European Parliament an bovine, ovine or caprine animals; and the a stunning by means of gas injected into the central nervous tissue by means of an elon	d of the Council ( <sup>6</sup> ) or mechanically se nimals from which the product is der cranial cavity or killed by the same m	eparated meat obtained from bones of rived have not been slaughtered after nethod or slaughtered by laceration of
		(²) or	[the product does not contain and is not der animals born, continuously reared and slaug decision in accordance with Article 5(2) of I	htered in a country or region classified	
Notes					
Part I:	:				
			son responsible for the consignment in the Eu filled in if the certificate is for import commod		d in only if it is a certificate for transit
	x refere thority.	nce I.11 and	I I.12: Approval number: the registration numb	er of the establishment or plant, whic	ch has been issued by the competent
			ace of destination: this box is to be filled in onl s, free warehouses and custom warehouses.	y if it is a certificate for transit comm	odity. The products in transit can only
			gistration number (railway wagons or containe reloading, the consignor must inform the bor		
— Во	x I.19:	use the appr	opriate Harmonized System (HS) code under	the following headings: 30.02 or 35.	.02.
— Во	x refere	ence I.23: for	bulk containers, the container number and th	ne seal number (if applicable) should	l be included.
— Bo	x refere	ence 1.25: teo	chnical use: any use other than for animal cor	nsumption.	
— Во	x refere	nce I.26 and	d I.27: fill in according to whether it is a transi	t or an import certificate.	
— Во	x refere	ence I.28 Sp	ecies: select from the following: Aves, Bovida	e, Suidae, Otra Mammalia, Pesca, R	Reptilia.

		Untreated blood products, exclu facture of derived products for p					
1.	INTRY Health information	for farmed animals II.a. Certificate reference No	Ш.Б.				
Par	t II:						
( <sup>1a</sup> )	OJ L 300, 14.11.2009, p. 1.						
( <sup>1b</sup> )	OJ L 54, 26.2.2011, p. 1.						
( <sup>2</sup> )	Delete as appropriate.						
( <sup>3</sup> )	<sup>(3)</sup> Code of the territory as it appears in Part 1 of Annex II to Regulation (EU) No 206/2010.						
(4)	( <sup>4</sup> ) In this case following the border check provided for in Directive 97/78/EC, and in accordance with the conditions laid down in Article 8(4) of that Directive, the products must be transported directly to the plant of destination.						
( <sup>5</sup> )	Code of the territory as it appears in Part 1 of Annex I to Regulation	on (EC) No 798/2008.					
( <sup>6</sup> )	OJ L 147, 31.5.2001, p. 1.						
-	The signature and the stamp must be in a different colour to that of	the printing.					
	Note for the person responsible for the consignment in the European I the consignment until it reaches the border inspection post.	Jnion: this certificate is only for veterina	ary purposes and has to accompany				
Off	cial veterinarian/Official inspector						
	Name (in capital letters):	Qualifica	tion and title:				
	Date:	Signatur	e:				
	Stamp:						

# [<sup>F1</sup>CHAPTER 4(D)

### Health certificate

For treated blood products, excluding of equidae, for the manufacture of derived products for purposes outside the feed chain for farmed animals, intended for dispatch to or for transit through  $\binom{2}{}$  the European Union]

cou	COUNTRY Veterinary certificate						
	l.1.	Consignor Name	I.2. Certificate reference No I.2.a.				
		Address	I.3. Central competent authority				
		Tel.	I.4. Local competent authority				
Part I: Details of dispatched consignment	1.5.	Consignee Name Address Postcode Tel. Country of origin ISO code I.8. Region of origin Code	I.6. Person responsible for the load in EU         Name         Address         Postcode         Tel.         I.9. Country of destination         ISO code         I.10. Region of destination				
of							
rt I: Details	1.11.	Place of origin Name Approval number Address	I.12. Place of destination Name Custom warehouse Address Approval number				
Ра		Name Approval number Address	Postcode				
		Name Approval number Address					
	I.13.	Place of loading	I.14. Date of departure				
	I.15.	Means of transport	I.16. Entry BIP in EU				
		Aeroplane					
		Road vehicle Other I	l.17.				
		Documentation references					
	I.18.	Description of commodity	I.19. Commodity code (HS code)				
			I.20. Quantity				
	1.21.	Temperature of product	I.22. Number of packages				
		Ambient Chilled	Frozen				
	1.23.	Seal/Container No	I.24. Type of packaging				
	1.25.	Commodities certified for:					
		Technical use					
	1.26.	For transit through EU to third country	I.27. For import or admission into EU				
	1.28.	Identification of the commodities					
		Species Approval number of (Scientific name) Manufacturin					

#### Treated blood products, excluding of equidae, for the manufacture of derived products for purposes outside the feed chain for farmed COUNTRY animals Ш. Health information II.a. Certificate reference No II.b. I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 of the European Parliament and of the Council (<sup>1a</sup>) and in particular Article 8(c) and (d) and Article 10 thereof, and Commission Regulation (EU) No 142/2011 (<sup>1b</sup>), and in particular Annex XIV, Chapter II thereof, and certify that: Certification II.1. the blood products described above consist of blood products that satisfy the requirements below; 11.2. they consist exclusively of blood products not intended for human or animal consumption; ≓ 11.3. they have been prepared and stored in a plant supervised by the competent authority, exclusively with the following animal by-products: Part [- blood of slaughtered animals, which is fit for human consumption in accordance with Union legislation, but is not intended for human consumption for commercial reasons;] (2) either [- blood of slaughtered animals, which is rejected as unfit for human consumption in accordance with Union legislation, but which did not show any signs of diseases communicable to humans or animals, derived from carcases that have been (<sup>2</sup>) and/or slaughtered in a slaughterhouse and were considered fit for human consumption following an ante-mortem inspection in accordance with Union legislation;] (2) and/or [- blood of slaughtered animals, which did not show any signs of diseases communicable to humans or animals, obtained from animals that have been slaughtered in a slaughterhouse after having been considered fit for human consumption following an ante-mortem inspection in accordance with Union legislation;] [- blood and blood products originating from live animals that did not show clinical signs of any disease communicable through these products to humans or animals;] (²) and/or [- animal by-products which have been derived from animals which have been submitted to illegal treatment as defined in Article 1(2)(d) of Directive 96/22/EC or Article 2(b) of Directive 96/23/EC;] (2) and/or [- animal by-products containing residues of other substances and environmental contaminants listed in Group B(3) of Annex I to Directive 96/23/EC, if such residues exceed the permitted levels laid down by Union legislation or, in the (²) and/or absence thereof, in national legislation;] the blood from which such products are manufactured has been collected in slaughterhouses approved in accordance with Union legislation, in slaughterhouses approved and supervised by the competent authority of the country of collection or from live animals in II.4. facilities approved and supervised by the competent authority of the country of collection. (2) [II.5. In case of blood products derived from Artiodactyla, Perissodactyla and Proboscidea including their crossbreeds, other than Suidae and Tayassuidae, the products have undergone one of the following treatments, guaranteeing the absence of pathogens of foot-and-mouth disease, vesicular stomatitis, rinderpest, peste des petits ruminants, Rift Valley fever and bluetongue: (2) either [heat treatment at a temperature of 65 °C for at least three hours, followed by an effectiveness check;] (2) and/or [irradiation at 25 kGy by gamma rays, followed by an effectiveness check;] (²) and/or [change in pH to pH 5 for two hours, followed by an effectiveness check;] (2) and/or [heat treatment of at least 80 °C throughout their substance, followed by an effectiveness check.]] (2) [II.6. In the case of blood products derived from Suidae, Tayassuidae, poultry and other avian species, the products have undergone one of the following treatments guaranteeing the absence of pathogens of the following diseases: foot-and-mouth disease, vesicular stomatitis, swine vesicular disease, classical swine fever, African swine fever, Newcastle disease and highly pathogenic avian influenza, as appropriate to the species: (2) either [heat treatment at a temperature of 65 °C for at least three hours, followed by an effectiveness check:] (2) and/or [irradiation at 25 kGy by gamma rays, followed by an effectiveness check;] [heat treatment of at least 80 °C for Suidae/Tayassuidae (2) and at least 70 °C for poultry and other avian species (2) (2) and/or throughout their substance, followed by an effectiveness check]].

COUNT	RY		Treated blood products, excluding of equidae, for the manufacture of derived products for purposes outside the feed chain for farmed animals				
11.	Health inform	nation	II.a. Certificate reference No	II.b.			
( <sup>2</sup> ) [II.7		of blood products derived from species other treatment (please specify):					
II.8.	The products were:						
	(²) either	[packed in new or sterilised bags or bottles;]					
	(²) or	[transported in bulk in containers or other means o approved by the competent authority before use;]		d and disinfected with a disinfectant			
	the outer pac	kaging or containers bear labels indicating "NOT F	FOR HUMAN OR ANIMAL CONSUM	PTION";			
11.9.	the products	were stored in enclosed storage;					
II.10.	all precaution	s were taken to avoid contamination of the produc	ts with pathogenic agents after treatn	nent;			
II.11.							
	(²) either	[the product does not contain and is not derived if 999/2001 of the European Parliament and of the C ovine or caprine animals; and the animals from w means of gas injected into the cranial cavity or ki tissue by means of an elongated rod-shaped inst	Council ( <sup>3</sup> ) or mechanically separated n which the product is derived have not illed by the same method or slaughter	neat obtained from bones of bovine, been slaughtered after stunning by red by laceration of central nervous			
	(²) or	[the product does not contain and is not derived animals born, continuously reared and slaughtere decision in accordance with Article 5(2) of Regula	d in a country or region classified as				
Notes							
Part I:							
		Person responsible for the consignment in the Eur be filled in if the certificate is for import commodi		in only if it is a certificate for transit			
	reference I.11 nority.	and I.12: Approval number: the registration number	er of the establishment or plant, which	has been issued by the competent			
		: Place of destination: this box is to be filled in only cones, free warehouses and custom warehouses.	r if it is a certificate for transit commod	lity. The products in transit can only			
		5: Registration number (railway wagons or containing and reloading, the consignor must inform the B		) or name (ship) is to be provided.			
— Box	I.19: use the	appropriate Harmonized System (HS) code under	the following headings: 05.11, 30.02	or 35.02.			
— Box	reference I.23	t for bulk containers, the container number and the	e seal number (if applicable) should b	be included.			
— Box	reference I.25	: technical use: any use other than for animal con	sumption.				
— Box	reference I.26	and I.27: fill in according to whether it is a transit	or an import certificate.				
— Box	reference 1.28	in case of Species: select from the following: Ave	es, Bovidae, Suidae, Otra Mammalia,	Pesca, Reptilia.			
Part II:							
( <sup>1a</sup> ) OJ	L 300, 14.11.	2009, p. 1.					
( <sup>1b</sup> ) OJ	L 54, 26.2.20	11, p. 1.					

		Treated blood products, excluding of equidae, for the manufacture of derived products for purposes outside the feed chain for farmed animals					
١١.	Health information	II.a. Certificate reference No	II.b.				
(2)	Delete as appropriate.						
(3)	( <sup>3</sup> ) OJ L 147, 31.5.2001, p. 1.						
-	The signature and the stamp must be in a different colour to that of	the printing.					
-	<ul> <li>Note for the person responsible for the consignment in the European Union: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.</li> </ul>						
Off	icial veterinarian/Official inspector						
	Name (in capital letters):	Qualif	cation and title:				
	Date:	Signal	ure:				
	Stamp:						

## CHAPTER 5(A)

## Health certificate

For fresh or chilled hides and skins of ungulates, intended for dispatch to or for transit through  $\binom{2}{2}$  the European Union

cou	NTR	Y	Veterinary certificate to El			
	l.1.	Consignor	I.2. Certificate reference No I.2.a.			
		Name	I.3. Central competent authority			
		Address				
		Tei.	I.4. Local competent authority			
Ŧ	1.5.	Consignee	I.6. Person responsible for the load in EU			
mer		Name	Name			
sign		Address	Address			
dispatched consignment		Postcode Tel.	Postcode Tel.			
tche						
f dispa	1.7.	Country of origin ISO code I.8. Region of origin Code	I.9. Country of ISO code I.10. Region of Code destination			
tails o	l.11.	Place of origin	I.12. Place of destination			
Part I: Details of		Name Approval number Address	Name Custom warehouse Address Approval number			
Ра		Name Approval number Address	Postcode			
		Name Approval number Address				
	I.13.	. Place of loading	I.14. Date of departure			
	l.15.	Means of transport	I.16. Entry BIP in EU			
		Aeroplane 🗌 Ship 🗌 Railway wagon 🗌				
		Road vehicle Other	I.17. Number(s) of CITES			
		Identification				
		Documentation references				
	I.18.	Description of commodity	I.19. Commodity code (HS code)			
			I.20. Quantity			
	I.21.	Temperature of product	I.22. Number of packages			
		Ambient Chilled	Frozen			
	1.23.	Seal/Container No	I.24. Type of packaging			
	1.25.	Commodities certified for:	I.			
		Animal feedingstuff Technical use				
	1.26.	For transit through EU to third country	I.27. For import or admission into EU			
	1.28.	Identification of the commodities				
		Species Approval number (Scientific name) Manufactu				

COUNTRY Fresh or chilled hides and					led hides and skins of ungulates				
	п.	Health inf	ormation	II.a. Certificate reference No	II.b.				
		Parliament	ersigned official veterinarian, declare that I have r and of the Council ( <sup>1a</sup> ) and in particular Article 10 the , Chapter II thereof, and certify that the hides and si	reof, and Commission Regulation (EU)					
	II.1.	have been obtained from animals that:							
ation		(2) either [- were slaughtered and their carcases are fit for human consumption in accordance with Union legislation;]							
Part II: Certification		( <sup>2</sup> ) or	( <sup>2</sup> ) or [- were slaughtered in a slaughterhouse, after undergoing ante-mortem inspection, and were considered fit, as a result of such inspection, for slaughter for human consumption in accordance with Union legislation;]						
Part II	II.2.		om a country or, in the case of regionalisation in acco gories of fresh meat of the corresponding species ar		part of a country from which imports				
		(a)	for at least 12 months before dispatch, has been fr	ee from the following diseases (3):					
			[- classical swine fever, and African swine fever;]						
			[- rinderpest;]						
		and							
		(b)	has been free for at least 12 months before dispatch no vaccination has been carried out against foot-ar		ere, for 12 months before dispatch,				
	11.3.	have been	obtained from:						
			at have remained in the territory of the country of originals less that three months old;]	in for at least three months before bei	ing slaughtered or since birth in the				
			e of hides and skins from bi-ungulates, animals that co the previous 30 days, and around which within a ra						
		disease in	e of hides and skins from swine, animals that come the previous 30 days, or of classical or African swine been no case of these diseases for 30 days;]						
			at have shown no evidence of [foot-and-mouth dise lisease] $(^3)$ during ante-mortem health inspection at t						
	11.4.	have unde	rgone all precautions to avoid contamination with pa	thogenic agents.					
	Notes								
Part I:									
— Box reference I.6: Person responsible for the consignment in the European Union: this box is to be filled in only if it is a certification commodity; it may be filled in if the certificate is for import commodity.									
	has been issued by the competent								
			12: Place of destination: this box is to be filled in only e zones, free warehouses and custom warehouses.	if it is a certificate for transit commod	ity. The products in transit can only				
			<ol> <li>Registration number (railway wagons or containe event of unloading and reloading.</li> </ol>	r and lorries), flight number (aircraft) o	or name (ship); information is to be				
	— Box	reference I	.19: use the appropriate HS code: 41.01; 41.02 or 4	1.03.					

# Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011. (See end of Document for details)

COUNTRY	Fresh or	chilled hides and skins of ungulates				
II. Health information	II.a. Certificate reference No	II.b.				
- Box reference I.23: for bulk containers, the container number and	- Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be given.					
- Box reference I.25: technical use: any use other than for animal	consumption.					
- Box reference I.26 and I.27: fill in according to whether it is a tra	nsit or an import certificate.					
Part II:						
( <sup>1a</sup> ) OJ L 300, 14.11.2009, p. 1.						
( <sup>1b</sup> ) OJ L 54, 26.2.2011, p. 1.						
( <sup>2</sup> ) Delete as appropriate.						
( <sup>3</sup> ) Delete diseases not applicable to the species concerned.						
- The signature and the stamp must be in a different colour to that	of the printing.					
<ul> <li>Note for the person responsible for the consignment in the Eu accompany the consignment until it reaches the border inspection</li> </ul>		ly for veterinary purposes and has to				
Official veterinarian/Official inspector						
Name (in capital letters):	Qualification and	d title:				
Date:	Signature:					
Stamp:						

## CHAPTER 5(B)

### Health certificate

For treated hides and skins of ungulates, intended for dispatch to or for transit through  $(^2)$  the European Union

cou	NTR	1	Veterinary certificate to EU			
	I.1.	Consignor	I.2. Certificate reference No I.2.a.			
		Name	I.3. Central competent authority			
		Address	I.4. Local competent authority			
		Tel.				
ent	1.5.	Consignee	I.6. Person responsible for the load in EU			
gnm		Name Address	Name Address			
onsi						
ed o		Postcode Tel.	Postcode Tel.			
dispatched consignment	17	Country of origin ISO code I.8. Region of origin Code	I.9. Country of ISO I.10. Region of Code			
disp	1.7.		destination code destination			
ls of						
Detai	1.11.	Place of origin	I.12. Place of destination			
Part I: Details		Name Approval number Address	Name Custom warehouse Address Approval number			
1		Name Approval number Address				
		Name Approval number	Postcode			
		Address				
	1.13.	Place of loading	I.14. Date of departure			
	l.15.	Means of transport	I.16. Entry BIP in EU			
		Aeroplane Ship Railway wagon Road vehicle Other	I.17. Number(s) of CITES			
		Identification				
		Documentation references				
	I.18.	Description of commodity	I.19. Commodity code (HS code)			
			I.20. Quantity			
	I.21.	Temperature of product	I.22. Number of packages			
		Ambient Chilled	Frozen			
	1.23.	Seal/Container No	I.24. Type of packaging			
	1.25.	Commodities certified for:				
		Animal feedingstuff Technical use				
	1.26.	For transit through EU to third country	I.27. For import or admission into EU			
		Third country ISO code				
	1.28.	Identification of the commodities	•			
		Species Approval number (Scientific name) Manufactu				

ou	INTRY			Trea	ted hides and skins of ungulates			
	П.	Health in	nformation	II.a. Certificate reference No	II.b.			
			Parliament	rsigned official veterinarian, declare that I have read and understood Regulation ( and of the Council ( <sup>1a</sup> ) and in particular Article 10 thereof, and Commission Regu Annex XIV, Chapter II thereof, and certify that the hides and skins described abo	lation (EU) No 142/2011 (1b), and in			
		II.1.	have beer	obtained from animals that:				
ication			(²) either	[- were slaughtered and their carcases are fit for human consumption in accord	dance with Union legislation;]			
Part II: Certification		( <sup>2</sup> ) or [- were slaughtered in a slaughterhouse, after undergoing ante-mortem inspection, and were consid result of such inspection, for slaughter for human consumption in accordance with Union legislation						
Part			(²) or	[- did not show any clinical signs of any disease communicable to humans or an were not killed to eradicate any epizootic disease;]	nimals through the hide or skin, and			
	( <sup>2</sup> ) eithe	r [II.2	part of a t	n animals originate from a third country or, in the case of regionalisation in accord hird country listed in Part 1 of Annex II to Commission Regulation (EU) No 206/2 e corresponding species are authorised and have been:				
			( <sup>2</sup> ) either	[dried;]				
			( <sup>2</sup> ) or	[dry-salted or wet-salted for at least 14 days prior to dispatch;]				
			(²) or	[dry-salted or wet-salted on the following date and transporter, the hides and skins will be transported by ship and the duration of have undergone a minimum of 14 days of salting before they reach the EU bo	transport will be such that they will			
			(²) or	[salted for seven days in sea salt with the addition of 2 $\%$ of sodium carbonate	;]			
			(²) or	[salted in sea salt with the addition of 2 % of sodium carbonate on the followin, and according to the declaration of the transporter, the hides and skins will be to of transport will be such that they will have undergone a minimum of seven days border inspection post.]]	ransported by ship and the duration			
	( <sup>2</sup> ) or	[11.2	part of a f	n animals originate from a third country or, in the case of regionalisation in accord third country listed in Part 1 of Annex II to Regulation (EU) No 206/2010 from ding species are NOT authorised and have been:				
			( <sup>2</sup> ) either	[salted for seven days in sea salt with the addition of 2 % of sodium carbonate	:]			
			( <sup>2</sup> ) or	[salted in sea salt with the addition of 2 % of sodium carbonate on the followin and according to the declaration of the transporter, the hides and skins will be to of transport will be such that they will have undergone a minimum of seven days border inspection post;]	ransported by ship and the duration			
			(²) or	[dried for 42 days at a temperature of at least 20 °C;]]				
		II.3.		nment has not been in contact with other animal products or with live animals pres ole disease.	senting a risk of spreading a serious			
	Notes							
	Part I:							
				responsible for the consignment in the European Union: this box is to be filled i d in if the certificate is for import commodity.	in only if it is a certificate for transi			
l								

COUNTRY	Trea	ted hides and skins of ungulates				
II. Health information	II.a. Certificate reference No	II.b.				
<ul> <li>Box reference I.11 and I.12: Approval number: the registration number authority.</li> </ul>	r of the establishment or plant, which	has been issued by the competent				
<ul> <li>Box reference I.12: Place of destination: this box is to be filled in only be stored in free zones, free warehouses and custom warehouses.</li> </ul>	Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.					
<ul> <li>Box reference I.15: Registration number (railway wagons or container provided in the event of unloading and reloading.</li> </ul>	and lorries), flight number (aircraft) or r	name (ship) and information is to be				
- Box reference I.19: use the appropriate HS code: 41.01; 41.02 or 41	.03.					
- Box reference I.23: for bulk containers, the container number and the	e seal number (if applicable) should b	e given.				
- Box reference I.25: technical use: any use other than for animal con-	sumption.					
- Box reference I.26 and I.27: fill in according to whether it is a transit	or an import certificate.					
Part II:						
( <sup>1a</sup> ) OJ L 300, 14.11.2009, p. 1.						
( <sup>1b</sup> ) OJ L 54, 26.2.2011, p. 1.						
( <sup>2</sup> ) Delete as appropriate.						
( <sup>3</sup> ) OJ L 73, 20.3.2010, p. 1.						
( <sup>4</sup> ) OJ L 147, 31.5.2001, p. 1.						
- The signature and the stamp must be in a different colour to that of	the printing.					
<ul> <li>Note for the person responsible for the consignment in the Europ accompany the consignment until it reaches the border inspection por</li> </ul>		or veterinary purposes and has to				
Official veterinarian/Official inspector						
Name (in capital letters):	Qualification and	d title:				
Date: Signature:						
Stamp:						

## CHAPTER 5(C)

### **Official declaration**

For treated hides and skins of ruminants and of equidae that are intended for dispatch to or for transit through  $(^1)$  the European Union and have been kept separate for 21 days or will undergo transport for 21 uninterrupted days before importation

cou	OUNTRY Veterinary certificate					
	l.1.	Consignor	I.2. Certificate reference No I.2.a.			
		Name	I.3. Central competent authority			
		Address				
		Tei.	I.4. Local competent authority			
ţ	I.5.	Consignee	I.6. Person responsible for the load in EU			
m		Name	Name			
nsig		Address	Address			
ched co		Postcode Tel.	Postcode Tel.			
of dispatched consignment	1.7.	Country of origin ISO code I.8. Region of origin Code	I.9. Country of ISO destination code destination			
I: Details	l.11.	Place of origin	I.12. Place of destination			
Part I: D		Name Approval number Address	Name Custom warehouse Address Approval number			
•		Name Approval number Address	Postcode			
		Name Approval number Address				
	I.13.	Place of loading	I.14. Date of departure			
	l.15.	Means of transport	I.16. Entry BIP in EU			
		Aeroplane Ship Railway wagon Road vehicle Other				
		Road vehicle Other I Identification Documentation references	I.17. Number(s) of CITES			
	l.18.	Description of commodity	I.19. Commodity code (HS code)			
			I.20. Quantity			
	I.21.	Temperature of product	I.22. Number of packages			
		Ambient Chilled	Frozen			
	1.23.	Seal/Container No	I.24. Type of packaging			
	1.25.	Commodities certified for:				
		Animal feedingstuff Technical use				
	1.26.	For transit through EU to third country	I.27. For import or admission into EU			
		Third country ISO code				
	1.28.	Identification of the commodities				
			Imber of establishments Net weight nufacturing plant			

col	JNTRY				Treated hides and skins of ruminar kept separate for 21 days or uninterrupted days before importa	will undergo transport for 21			
	П.	Heal	th information	on	II.a. Certificate reference No	II.b.			
	I, the undersigned declare that the hides and skins described above:								
		II.1.	have been	obtained from animals that:					
	(1) either [- were slaughtered and their carcases are fit for human consumption in accordance with Union le								
(1) or [- were slaughtered in a slaughterhouse, after undergoing ante-mortem inspection, and were con result of such inspection, for slaughter for human consumption in accordance with Union legitive									
Part II: Certification			( <sup>1</sup> ) or	[- did not show any clinical signs of an and were not killed to eradicate any		or animals through the hide or skin,			
art II		II.2.	have been:						
1			(1) either	[- dried;]					
			( <sup>1</sup> ) or	[- dry-salted or wet-salted for at least	14 days prior to dispatch;]				
			( <sup>1</sup> ) or	[- salted for seven days in sea salt wit	th the addition of 2 % of sodium carbo	onate;]			
		II.3.		been in contact with other animal pro le disease;	ducts or with live animals presentir	ng a risk or spreading a serious			
	( <sup>2</sup> ) either	[11.4.		have been kept separate immediately before dispatch for 21 days under official supervision after the treatment described under point II.2.]					
	(²) or	[11.4.	following th	e declaration of the transporter, the dur	ation of the transport period is foresed	en to be at least 21 days.]			
	Notes								
	Part I:								
				sponsible for the consignment in the Eu n if the certificate is for import commodi		n only if it is a certificate for transit			
	- Box refer authority.		11 and I.12:	Approval number: the registration numbe	er of the establishment or plant, which	has been issued by the competent			
				destination: this box is to be filled in only warehouses and custom warehouses.	r if it is a certificate for transit commod	ity. The products in transit can only			
				ion number (railway wagons or containe pading and reloading.	r and lorries), flight number (aircraft) o	or name (ship); information is to be			
	- Box refer	ence I.	19: use the a	appropriate HS code: 41.01; 41.02 or 4	1.03.				
	- Box refer	ence I.	23: for bulk	containers, the container number and th	e seal number (if applicable) should b	e given.			
	- Box refer	ence I.	25: technical	use: any use other than for animal con	sumption.				
	- Box refer	ence I.	26 and I.27:	fill in according to whether it is a transi	t or an import certificate.				
	Part II:								
	(1) Delete as	s appro	priate.						
	— The sign	ature a	nd the stamp	must be in a different colour to that of	the printing.				
	- Note for accompa	the pe ny the	rson respons consignment	sible for the consignment in the Europe until it reaches the border inspection p	ean Union: This declaration is only fo ost.	or veterinary purposes and has to			

# Treated hides and skins of ruminants and of equidae that have been kept separate for 21 days or will undergo transport for 21 uninterrupted days before importation

П.	Health information	II.a. Certificate reference No	II.b.				
Offic	Official veterinarian/Official inspector						
	Name (in capital letters):	Qualification and title:					
	Date:	Signature:					
	Stamp:						

# [<sup>F1</sup>CHAPTER 6(A)

### Health certificate

For treated game trophies and other preparations of birds and ungulates, consisting only of bones, horns, hooves, claws, antlers, teeth, hides or skins, for dispatch to or for transit through  $\binom{2}{1}$  the European Union]

COUNTRY

cou	JNTRY Veterinary certificate to EU						
	l.1.	Consignor Name	I.2. Certificate reference No I.2.a.				
		Address	I.3. Central competent authority				
		Tel.	I.4. Local competent authority				
dispatched consignment	1.5.	Consignee Name Address Postcode Tel.	I.6. Person responsible for the load in EU Name Address Postcode Tel.				
of dispat	1.7.	Country of origin ISO code I.8. Region of origin Code	I.9. Country of ISO code I.10. Region of Code destination				
ails o	1.11.	Place of origin	I.12. Place of destination				
t I: Details		Name Approval number Address	Name Custom warehouse Address Approval number				
Part		Name Approval number Address	Postcode				
		Name Approval number Address					
	I.13.	Place of loading	I.14. Date of departure				
	l.15.	Means of transport	I.16. Entry BIP in EU				
		Aeroplane Ship Railway wagon Road vehicle Other					
		Identification Documentation references	I.17. Number(s) of CITES				
	l.18.	Description of commodity	I.19. Commodity code (HS code)				
			I.20. Quantity				
	1.21.		I.22. Number of packages				
	1.23.	Seal/Container No	I.24. Type of packaging				
	1.25.	Commodities certified for:					
		Technical use					
	1.26.	For transit through EU to third country	I.27. For import or admission into EU				
	1.28.	Identification of the commodities					
		Species Nature c (Scientific name)	f commodity Number of packages				

cou	JNTRY				Treated game trophies and other lates, consisting only bones, horr hides or skins	
	п. н	ealth info	rmation		II.a. Certificate reference No	II.b.
uo			European F		hat I have read and understood Reg Commission Regulation (EU) No 142 trophies described above:	
Part II: Certification		II.1.		have been packaged, immediately after treatment, without being in contact with other products of animal origin likely to contaminate them, in individual, transparent and closed packages so as to avoid any subsequent contamination;		
t II: Ce	( <sup>2</sup> ) either	[II.2.1	in the case	of game trophies or other preparations	s consisting only of hides or skin:	
Par			(²) either	[have been dried;]		
			(²) and/or	[have been dry-salted or wet-salted for	or a minimum of 14 days before dispat	ch;]
			(²) and/or	porter, will be transported by ship and	d the duration of the transport will be su ey reach the EU border inspection pos	ich that they will have undergone a
	(²) and/or	[11.2.2	in the case	of game trophies or other preparations	s consisting only of bone, horns, hoove	es, claws, antlers or teeth:
				een immersed in boiling water for an a , claws, antlers or teeth is removed, an	appropriate time so as to ensure that a nd	any matter other than bone, horns,
				een disinfected with a product authoris onsisting of bone are concerned.]	ed by the competent authority, in partic	ular with hydrogen peroxide where
	Notes					
	Part I:					
				sponsible for the consignment in the Eu n if the certificate is for import commo	uropean Union: this box is to be filled i lity.	n only if it is a certificate for transit
	- Box ref authorit		1 and I.12: /	Approval number: the registration numb	er of the establishment or plant, which	has been issued by the competent
				destination: this box is to be filled in on warehouses and custom warehouses.	ly if it is a certificate for transit commod	ity. The products in transit can only
				on number (railway wagons or contain ing, the consignor must inform the BIP	er and lorries), flight number (aircraft) c of entry into the EU.	or name (ship) is to be provided. In
	— Box I.1	9: use the	e appropriate	Harmonized System (HS) code under	the following headings: 05.05, 05.06,	05.07 or 97.05.
	- Box ref	erence I.2	23: for bulk o	containers, the container number and th	he seal number (if applicable) should b	e included.
	- Box ref	erence I.2	25: technical	use: any use other than for animal con	nsumption.	
	- Box ref	erence I.2	26 and I.27:	fill in according to whether it is a trans	it or an import certificate.	
	- Box ref	erence I.2	28:			
	(a) for	nature of	commodity,	select one or more of the following:	[bones], [horns], [hooves], [claws], [ant	lers], [teeth], [hides] and/or [skins];
				ct from the following: Aves, Equidae, T dae, Moschidae Suidae, Tayassuidae, T	Tapiridae, Rhinoceritidae, Antilocaparida Tragulidae and Elephantidae.	ae, Bovidae, Camelidae, Cervidae,
	Part II:					
	( <sup>1a</sup> ) OJ L	300, 14.1	1.2009, p. 1			

COUNTRY		r preparations of birds and ungu- ms, hooves, claws, antiers, teeth,				
II. Health information	II.a. Certificate reference No	II.b.				
( <sup>1b</sup> ) OJ L 54, 26.2.2011, p. 1						
( <sup>2</sup> ) Delete as appropriate.						
- The signature and the stamp must be in a different colour to that of	the printing.					
<ul> <li>Note for the person responsible for the consignment in the European I the consignment until it reaches the border inspection post.</li> </ul>	Jnion: this certificate is only for veterin	ary purposes and has to accompany				
Official veterinarian/Official inspector						
Name (in capital letters):	Qualific	ation and title:				
Date:	Date: Signature:					
Stamp:						

### CHAPTER 6(B)

## Health certificate

For game trophies or other preparations of birds and ungulates consisting of entire parts not having been treated, intended for dispatch to or for transit through  $(^2)$  the European Union

cou	NTR	<i>,</i>	Veterinary certificate to EL			
	I.1.	Consignor	I.2. Certificate reference No I.2.a.			
		Name	I.3. Central competent authority			
		Address				
		Tel.	I.4. Local competent authority			
ŧ	1.5.	Consignee	I.6. Person responsible for the load in EU			
ame		Name	Name			
nsigı		Address	Address			
dispatched consignment		Postcode Tel.	Postcode Tel.			
of dispatc	1.7.	Country of origin ISO code I.8. Region of origin Code	I.9. Country of ISO destination code destination			
etails	l.11.	Place of origin	I.12. Place of destination			
Part I: Details		Name Approval number Address	Name Custom warehouse Address Approval number			
<b>a</b>		Name Approval number Address	Postcode			
		Name Approval number Address				
	I.13.	Place of loading	I.14. Date of departure			
	l.15.	Means of transport	I.16. Entry BIP in EU			
		Aeroplane 🗌 Ship 🗌 Railway wagon 🗌				
		Road vehicle Other I Identification	I.17. Number(s) of CITES			
	I.18.	Description of commodity	I.19. Commodity code (HS code)			
			I.20. Quantity			
	1.21		I.22. Number of packages			
	1.23.	Seal/Container No	I.24. Type of packaging			
	1.25.	Commodities certified for:				
		Technical use				
	1.26.	For transit through EU to third country	I.27. For import or admission into EU			
		Third country ISO code				
	1.28.	Identification of the commodities				
		Species (Scientific name)	Number of packages			

со	DUNTRY				Game trophies or other prepara consisting of entire parts not havin						
	П. Н	ealth in	formation	ı	II.a. Certificate reference No	II.b.					
		Parliar	ment and	ed official veterinarian, declare that I have of the Council ( <sup>1a</sup> ) and Commission Regu tify that the game trophies described above:	lation (EU) No 142/2011 (1b), and in						
r.	( <sup>2</sup> ) either	[II.1.	with respe	ect to game trophies or other preparations of	ns of cloven-hoofed animals, excluding swine:						
Part II: Certification				(region) has been free from foot-and-mouth disease and rinderpest for the previous 12 months, and during period, no vaccination against any of those diseases has taken place; and							
u II	(b) the game trophies or other preparations described above:										
Ра	<ul> <li>(i) were obtained from animals which were killed in the territory of that region, which is authorised for export of free the corresponding susceptible domestic species and where, during the last 60 days, there have been no anim restrictions because of outbreaks of diseases to which the game animals are susceptible; and</li> </ul>										
				ginated from animals that were killed at a dis hird country not authorised to export untreate							
	(²) or	[11.1.	with respe	ect to game trophies or other preparations of	f wild swine:						
			diseas	(region) during the last 12 montrise, foot-and-mouth disease and porcine enter d out against any of those diseases during t	oviral encephalmiyelitis (Teschen disea						
			(b) the ga	ame trophies or other preparations described	l above:						
	<ul> <li>(i) were obtained from animals which were kill corresponding susceptible domestic species restrictions because of outbreaks of diseases</li> </ul>				and where, during the last 60 days, t	there have been no animal health					
				ginated from animals that were killed at a dis third country not authorised to export untreat							
	( <sup>2</sup> ) or			ect to game trophies or other preparations of from wild solipeds that were killed in the terr							
	( <sup>2</sup> ) or	[  .1.	with respe	ect to game trophies or other preparations of	f game birds:						
			(a)	(region) is free from highly path	ogenic avian influenza and Newcastle	disease; and					
			and w	ame trophies or other preparations described where during the last 30 days there have bee Id birds are susceptible;]							
		a		trophies or other preparations described ab gin likely to contaminate them, in individual, t							
		II.3.									
		(*	<sup>2</sup> ) either	[the product does not contain and is not der No 999/2001 of the European Parliament ar of bovine, ovine or caprine animals; and th after stunning by means of gas injected i laceration of central nervous tissue by me cavity.]	nd of the Council ( <sup>3</sup> ) or mechanically se e animals from which this product is on nto the cranial cavity or killed by the	parated meat obtained from bones derived have not been slaughtered a same method or slaughtered by					
		(*	<sup>2</sup> ) or	[the product does not contain and is not der animals born, continuously reared and slaug a decision in accordance with Article 5(2) of	htered in a country or region classified						

# Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011. (See end of Document for details)

COUNTRY Game trophies or other preparations of birds and consisting of entire parts not having been treated				
II. Health information	II.a. Certificate reference No	II.b.		
Notes				
Part I:				
Box reference I.6: Person responsible for the consignment in the European Union: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.				
Box reference I.11 and I.12: Approval number: the registration number of the establishment or plant, which has been issued by the competent authority.				
<ul> <li>Box reference I.12: Place of destination: this box is to be filled in on be stored in free zones, free warehouses and custom warehouses.</li> </ul>	ly if it is a certificate for transit commo	dity. The products in transit can only		
<ul> <li>Box reference I.15: Registration number (railway wagons or contain provided in case of unloading and reloading.</li> </ul>	er and lorries), flight number (aircraft)	or name (ship); information is to be		
- Box reference I.19: use the appropriate HS code: 05.05; 05.06 or (	05.07.			
- Box reference I.23: for bulk containers, the container number and t	he seal number (if applicable) should	be included.		
- Box reference I.25: technical use: any use other than for animal co	nsumption.			
- Box reference I.26 and I.27: fill in according to whether it is a trans	it or an import certificate.			
Part II:				
( <sup>1a</sup> ) OJ L 300, 14.11.2009, p. 1.				
( <sup>1b</sup> ) OJ L 54, 26.2.2011, p. 1.				
( <sup>2</sup> ) Delete as appropriate.				
( <sup>3</sup> ) OJ L 147, 31.5.2001, p. 1.				
- The signature and the stamp must be in a different colour to that o	f the printing.			
<ul> <li>Note for the person responsible for the consignment in the European the consignment until it reaches the border inspection post.</li> </ul>	Union: this certificate is only for veterin	nary purposes and has to accompany		
Official veterinarian/Official inspector				
Name (in capital letters):	Qualification a	nd title:		
Date:	Signature:			
Stamp:				

### CHAPTER 7(A)

### Health certificate

For pig bristles from third countries or regions thereof that are free from African swine fever, intended for dispatch to or for transit through  $\binom{2}{1}$  the European Union

cou	NTR	(	Veterinary certificate to EU
	l.1.	Consignor Name	I.2. Certificate reference No     I.2.a.       I.3. Central competent authority
		Address	
		Tel.	I.4. Local competent authority
ent	1.5.	Consignee	I.6. Person responsible for the load in EU
Bnm		Name	Name
onsi		Address	Address
dispatched consignment		Postcode Tel.	Postcode Tel.
5	1.7.	Country of origin ISO code I.8. Region of origin Code	I.9. Country of ISO I.10. Region of Code destination code destination
etails	1.11.	Place of origin	I.12. Place of destination
Part I: Details		Name Approval number Address	Name Custom warehouse Address Approval number
۵ ۵		Name Approval number Address	
		Name Approval number Address	Postcode
	1.13.	Place of loading	I.14. Date of departure
	I.15.	Means of transport	I.16. Entry BIP in EU
		Aeroplane Ship Railway wagon Road vehicle Other	
		Road vehicle Other I Identification	1.17.
		Documentation references	
	1.18.	Description of commodity	1.19. Commodity code (HS code) 05.02
			I.20. Quantity
	1.21.	Temperature of product	I.22. Number of packages
		Ambient Chilled	Frozen
	1.23.	Seal/Container No	I.24. Type of packaging
	1.25.	Commodities certified for:	
		Animal feedingstuff	
	1.26.	For transit through EU to third country	I.27. For import or admission into EU
		Third country ISO code	
	1.28.	Identification of the commodities	
		Approval number of establishments Nu Manufacturing plant	mber of packages Net weight

COUNTRY			Pig bristles from third countries or regions thereof that are free from African swine fever				
	П.	Health information	II.a. Certificate reference No	II.b.			
		I, the undersigned official veterinarian, declare that I have read at and of the Council ( <sup>1a</sup> ) and in particular Article 10(b)(iv) thereof, a XIV, Chapter II thereof, and certify that:					
	II.1. the pig bristles described above have been obtained from pigs originating, and slaughtered in a slaughterhouse, in the country of o						
ation	II.2. the pigs, from which the pig bristles have been obtained, did not show during inspection, carried out at the time of slaughtering, signs of diseases communicable to humans or animals and were not killed to eradicate any epizootic disease;						
Part II: Certification	II.3. the country of origin or, in case of regionalisation according to Union legislation, the region of origin, has been free from African swine feve for at least 12 months;						
art II:	II.4. the pig bristles are dry and securely enclosed in packaging.						
	Notes						
	Part I:						
		reference I.6: Person responsible for the consignment in the Eur modity; it may be filled in if the certificate is for import commodit		n only if it is a certificate for transit			
		reference I.11 and I.12: Approval number: the registration numbe ority.	er of the establishment or plant, which	has been issued by the competent			
	- Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.						
		reference I.15: Registration number (railway wagons or contained in case of unloading and reloading.	r and lorries), flight number (aircraft) c	or name (ship); information is to be			
	— Box	reference I.23: for bulk containers, the container number and the	e seal number (if applicable) should b	e included.			
	— Box	reference I.25: technical use: any use other than for animal con-	sumption.				
	— Box	reference I.26 and I.27: fill in according to whether it is a transit	t or an import certificate.				
	— Box	reference I.28: Manufacturing plant: provide the veterinary control	ol number of the registered establishm	ent.			
	Part II:						
	( <sup>1a</sup> ) OJ	J L 300, 14.11.2009, p. 1.					
	( <sup>1b</sup> ) OJ	J L 54, 26.2.2011, p. 1.					
	(²) De	elete as appropriate.					
	— The	signature and the stamp must be in a different colour to that of	the printing.				
		e for the person responsible for the consignment in the European U consignment until it reaches the border inspection post.	Jnion: this certificate is only for veterina	ry purposes and has to accompany			
	Official	veterinarian/Official inspector					
	Na	me (in capital letters):	Qualification and	i title:			
	Da	te:	Signature:				
	Sta	amp:					

### CHAPTER 7(B)

### Health certificate

For pig bristles from third countries or regions thereof that are not free from African swine fever, intended for dispatch to or for transit through (<sup>2</sup>) the European Union COUNTRY

.00	NINI		veterinary certificate to EC			
	l.1.		I.2. Certificate reference No I.2.a.			
		Name Address	I.3. Central competent authority			
		Tel.	I.4. Local competent authority			
÷	1.5.	Consignee	I.6. Person responsible for the load in EU			
e		Name	Name			
<u>B</u>		Address	Address			
nsi l		Address	Address			
Part I: Details of dispatched consignment		Postcode Tel.	Postcode Tel.			
spa	1.7.	Country of origin ISO code I.8. Region of origin Code	I.9. Country of ISO I.10. Region of Code			
ΰ			destination code destination			
e.						
Details	l.11.	Place of origin	I.12. Place of destination			
÷		Name Approval number	Name Custom warehouse Address Approval number			
Par		Address				
		Name Approval number Address				
			Postcode			
		Name Approval number Address				
Ì	113	Place of loading	I.14. Date of departure			
	1.10.					
	l.15.	Means of transport	I.16. Entry BIP in EU			
		Aeroplane 🗌 Ship 🗌 Railway wagon 🗌				
		Road vehicle Other	1.17.			
		Identification				
		Documentation references				
	I.18.	Description of commodity	I.19. Commodity code (HS code) 05.02			
			I.20. Quantity			
	1.21.	Temperature of product	I.22. Number of packages			
		Ambient Chilled	Frozen			
	1.23.	Seal/Container No	I.24. Type of packaging			
	1.25.	Commodities certified for:				
		Animal feedingstuff Technical use				
	1.26.	For transit through EU to third country	I.27. For import or admission into EU			
		Third country ISO code				
	1.28.	Identification of the commodities				
		Approval number of establishments Num Manufacturing plant	ber of packages Net weight			

co	JNTRY			Pig bristles from third countries or from African swine fever	regions thereof that are not free			
	II. Health information			II.a. Certificate reference No	II.b.			
		and of the	rsigned official veterinarian, declare that I have read a Council ( <sup>1a</sup> ) and in particular Article 10(b)(iv) thereof, a ter II thereof, and certify that:					
	II.1.	the pig bri	stles described above have been obtained from pigs	originating, and slaughtered in a slaug	hterhouse, in the country of origin;			
Part II: Certification	II.2.		om which the pig bristles have been obtained did not communicable to humans or animals and were not kill					
: Cert	II.3.	I.3. the pig bristles mentioned above have been:						
Part II		( <sup>2</sup> ) either	[boiled;]					
		(²) or	[dyed;]					
		(²) or	[bleached;]					
	II.4.	the pig bri	stles are dry and securely enclosed in packaging.					
	Notes							
	Part I:							
			.6: Person responsible for the consignment in the Eu nay be filled in if the certificate is for import commodi		n only if it is a certificate for transit			
		reference I. ority.	.11 and I.12: Approval number: the registration number	er of the establishment or plant, which	has been issued by the competent			
	— Box be s	reference I. tored in fre	.12: Place of destination: this box is to be filled in only e zones, free warehouses and custom warehouses.	r if it is a certificate for transit commodi	ty. The products in transit can only			
			.15: Registration number (railway wagons or containe e of unloading and reloading.	r and lorries), flight number (aircraft) o	r name (ship); information is to be			
	— Box	reference I	.23: for bulk containers, the container number and the	e seal number (if applicable) should be	e included.			
	— Box	reference I	.25: technical use: any use other than for animal con	sumption.				
	— Box	reference I	.26 and I.27: fill in according to whether it is a transit	t or an import certificate.				
	— Box	reference I	.28: Manufacturing plant: provide the veterinary contro	ol number of the registered establishm	ent.			
	Part II:							
	( <sup>1a</sup> ) OJ	L 300, 14.	11.2009, p. 1.					
	( <sup>1b</sup> ) OJ	L 54, 26.2.	2011, p. 1.					
	( <sup>2</sup> ) Del	ete as appr	ropriate.					
	— The	signature a	and the stamp must be in a different colour to that of	the printing.				
			son responsible for the consignment in the European U it until it reaches the border inspection post.	Jnion: this certificate is only for veterina	ry purposes and has to accompany			

COUNTRY	Pig bristles from third countries of from African swine fever	Pig bristles from third countries or regions thereof that are not free from African swine fever					
II. Health information	II.a. Certificate reference No	II.b.					
Official veterinarian/Official inspector							
Name (in capital letters):	Qualification ar	nd title:					
Date:	Signature:						
Stamp:							

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011. (See end of Document for details)

# [<sup>F14</sup>CHAPTER 8

### Health certificate

# for animal by-products to be used for purposes outside the feed chain or for trade samples (<sup>2</sup>), intended for dispatch to or for transit through (<sup>2</sup>) the European Union]

COU	NTR	1	Veterinary certificate to EU			
	l.1.	Consignor Name	I.2. Certificate reference No I.2.a.			
		Address	I.3. Central competent authority			
		Tel.	I.4. Local competent authority			
ignment	1.5.	Consignee Name Address	I.6. Person responsible for the load in EU Name Address			
Part I: Details of dispatched consignment		Postcode Tel.	Postcode Tel.			
of dispatc	1.7.	Country of ISO code I.8. Region of Code origin Code	I.9. Country of ISO code I.10. Region of Code destination			
ils	I.11.	Place of origin	I.12. Place of destination			
I: Deta		Name Approval number Address	Name Custom warehouse Address Approval number			
Part		Name Approval number Address	Postcode			
		Name Approval number Address				
	I.13.	Place of loading	I.14. Date of departure			
	l.15.	Means of transport	I.16. Entry BIP in EU			
		Aeroplane         Ship         Railway wagon           Road vehicle         Other				
		Identification	l.17.			
		Documentation references				
	l.18.	Description of commodity	I.19. Commodity code (HS code)			
			I.20. Quantity			
	1.21.	Temperature of product	I.22. Number of packages			
		Ambient Chilled	Frozen			
	1.23.	Seal/Container No	I.24. Type of packaging			
	1.25.	Commodities certified for:				
		Technical use	1			
	1.26.	For transit through EU to third country	I.27. For import or admission into EU			
	1.00					
	1.28.	Identification of the commodities				
		Species Nature of Approval number of (Scientific name) commodity Manufacturin				

	NTRY II.	Health information		r for trade samples (2) II.a. Certificate reference No	II.b.
'		nealth information	' L	n.a. Certificate reference No	11.0.
		Parliament an	gned official veterinarian, declare that I have d of the Council ( <sup>1a</sup> ) and Commission Regulation at the animal by-products described above:		
	( <sup>2</sup> ) II.1.		nples which consist of animal by-products inter o Commission Regulation (EU) No 142/201 ON'; or		
(	( <sup>2</sup> ) II.2.	satisfy the an	imal health requirements below;		
1	II.2.1.	have been			
		( <sup>2</sup> ) either [(a	) obtained from materials imported from thirr to export fresh meat of the species to the		(3) authorise
		( <sup>2</sup> ) and/or [(b	) obtained in the exporting country, territory	or part thereof:	
			either		
			<ul> <li>(i) That have remained in this territory or birth or for at least the last three mont</li> </ul>		meat of the species to the EU since
			(ii) Killed in the wild in this territory (4);]		
		( <sup>2</sup> ) and/or [(c	) are derived from eggs, milk, rodents, lagor	morphs, or aquatic animals or terr	estrial or aquatic invertebrates;]
	11.2.2.		e of materials other than derived from eggs, have been obtained from animals:	milk, rodents, lagomorphs, or aq	uatic animals or terrestrial or aqual
		( <sup>2</sup> ) either [(a	) coming from holdings:		
			(i) where, for the following diseases for wh rinderpest, swine vesicular disease, Ne days, nor of classical or African swine f within 10 km, during the prior 30 days;	ewcastle disease or highly pathoge ever during the prior 40 days; nor	nic avian influenza during the prior 3
			<ul><li>(ii) where there has been neither case/ou holdings situated in their vicinity within</li></ul>		
		(b)	which:		
			(i) were not killed to eradicate any epizod	otic disease;	
			<ul> <li>(ii) have remained in their holdings of origin directly to the slaughterhouse without conditions;</li> </ul>		
			(iii) at the slaughterhouse, have passed the and have shown no evidence of the optimized in the optimized states.		
			(iv) have been handled in the slaughterhou relevant provisions of Union legislation Chapters II and III of Council Regulation	n and have met requirements at le	
		(²) or [(a	) captured and killed in the wild in an area:		
			<ul> <li>(i) in which within 25 km there has been are susceptible: foot-and-mouth diseas during the prior 30 days nor of classical</li> </ul>	se, rinderpest, Newcastle disease	or highly pathogenic avian influent
			<li>(ii) that is situated at a distance that excer part thereof, which is not authorised a</li>		
		(b)	which after killing were transported within afterwards to a game establishment, or dir		a collection centre and immediate

COUNT	RY		Animal by-products to be used for or for trade samples ( <sup>2</sup> )	purposes outside the feed chain
П.	Health information		II.a. Certificate reference No	II.b.
II.2.3.	establishment which the anim exportation to	e of materials other than materials derive around which, within a radius of 10 km, the nals are susceptible during the prior 30 days the European Union has been authorised or under the control of an official veterinarian;	ere has been no case/outbreak of dis s or, in the event of a case of disease	eases referred to in point II.2.2 for , the preparation of raw material for
II.2.4.		ained and prepared without contact with oth so as to avoid contamination with pathogen		nditions required above, and it has
II.2.5.	and, in the cas authority, beari	cked in new packaging preventing any leak se of consignments shipped other than via p ing the label indicating 'ANIMAL BY-PRODU DE THE FEED CHAIN' and the name and a	arcel post, in containers sealed under ICTS ONLY FOR THE MANUFACTUR	the responsibility of the competent RE OF DERIVED PRODUCTS FOR
II.2.6.	consist only of	the following animal by-products:		
		carcasses and parts of animals slaughtered fit for human consumption in accordance commercial reasons;]		
	., -	carcasses and the following parts originating were considered fit for slaughter for huma following parts of animals from game killed	an consumption following an ante-mo	rtem inspection or bodies and the
		<ul> <li>(i) carcasses or bodies and parts of anima Union legislation, but which did not show</li> </ul>		
		(ii) heads of poultry;		
		<li>(iii) hides and skins, including trimmings an and metacarpus bones, tarsus and me</li>		uding the phalanges and the carpus
		(iv) pig bristles;		
		(v) feathers;]		
	( <sup>2</sup> ) and/or [-	animal by-products from poultry and lagomo (EC) No 853/2004, which did not show any		
	( <sup>2</sup> ) and/or [-	blood of animals which did not show any obtained from animals other than ruminar considered fit for slaughter for human con- legislation;]	nts that have been slaughtered in a	slaughterhouse after having been
	( <sup>2</sup> ) and/or [-	animal by-products arising from the product bone, greaves and centrifuge or separator		consumption, including degreased
	( <sup>2</sup> ) and/or [-	products of animal origin, or foodstuffs cont consumption for commercial reasons or due which no risk to public or animal health ari	to problems of manufacturing or pack	
	( <sup>2</sup> ) and/or [-	pet food and feedingstuffs of animal origin, are no longer intended for feeding for comn or other defects from which no risk to publ	nercial reasons or due to problems of	
	( <sup>2</sup> ) and/or [-	blood, placenta, wool, feathers, hair, horns signs of any disease communicable throug		
	( <sup>2</sup> ) and/or [-	aquatic animals, and parts of such anima communicable to humans or animals;]	als, except sea mammals, which did	I not show any signs of diseases
	( <sup>2</sup> ) and/or [-	animal by-products from aquatic animals or consumption;]	iginating from establishments or plants	s manufacturing products for human

COUNTRY				Animal by-products to be used for or for trade samples ( <sup>2</sup> )	r purposes outside the feed cha
ll. Heal	th informa	tion		II.a. Certificate reference No	II.b.
	(²) and/or		the following material originating from anim material to humans or animals:	hals which did not show any signs of	disease communicable through the
			(i) shells from shellfish with soft tissue or	flesh;	
			(ii) the following originating from terrestria	I animals:	
			- hatchery by-products,		
			— eggs,		
			- egg by-products, including egg she	ilis;	
			(iii) day-old chicks killed for commercial re	pasons;]	
	(²) and/or	[-	animal by-products from aquatic or terrest	rial invertebrates, other than species	pathogenic to humans or animals
	(²) and/or	-	animals and parts thereof of the zoologic referred to in Article 8(a)(iii), (iv) and (v) o in Article 9(a) to (g) of that Regulation;]		
	(²) and/or		fur originating from dead animals that did no humans or animals;]	ot show clinical signs of any disease co	ommunicable through that product t
II.2.7.			p-frozen at the plant of origin or have beer en dispatch and delivery to the plant of de		gislation in such a way that they w
( <sup>2</sup> ) ( <sup>5</sup> ) [II.2.8.	Specific requirements				
( <sup>2</sup> ) ( <sup>6</sup> ) II.2.8.1.	The by-products in this consignment come from animals that have been obtained in the territory mentioned under (II.2.1), where vaccination programmes against foot-and-mouth disease are being regularly carried out and officially controlled in domestic bovir animals.				
	The by-pr	oduct	s in this consignment consist of animal by	-products derived from offal or debon	ned meat.]
II.2.9.					
	(²) either	999/ bovi stun	product does not contain and is not derived 2001 of the European Parliament and of ne, ovine or caprine animals; and the anir ning by means of gas injected into the cra ral nervous tissue by means of an elongat	the Council ( <sup>8</sup> ) or mechanically sepa mals from which this product is deriv anial cavity or killed by the same met	rated meat obtained from bones of ed have not been slaughtered after thod or slaughtered by laceration of
	(²) or	anin	product does not contain and is not derive hals born, continuously reared and slaughte sion in accordance with Article 5(2) of Reg	ared in a country or region classified a	
II.2.10.	in addition	as r	egards TSE:		
	( <sup>2</sup> ) either	origi the l	ase of animal by-products intended for fee n, the ovine and caprine animals from which ast three years on a holding where no offic satisfied the following requirements for the	n these products are derived have bee sial movement restriction is imposed d	in kept continuously since birth or fo
		(i)	it has been subject to regular official veter	inary checks;	
			no classical scrapie case, as defined in po or, following the confirmation of a classical		) No 999/2001, has been diagnose
			- all animals in which classical scrapie w	ras confirmed have been killed and d	lestroyed, and
			<ul> <li>all goats and sheep on the holding have genotype and breeding ewes carrying a</li> </ul>		
			ovine and caprine animals, with the except holding only if they come from a holding w		

0	UNTRY	Animal by-products to be used for purposes outside the feed chain or for trade samples $(^2\!)$		
II.	Health information	II.a. Certificate reference No	II.b.	
	( <sup>2</sup> ) or [in case of animal by-products intended for f origin, and destined to a Member State listed caprine animals from which these products are on a holding where no official movement res following requirements for the last seven year	in the Annex to Commission Regulation e derived have been kept continuously triction is imposed due to a suspicior	n (EC) No 546/2006 ( <sup>9</sup> ), the ovine and since birth or for the last seven years	
	(i) it has been subject to regular official vete	erinary checks;		
	<ul> <li>(ii) no classical scrapie case, as defined in po following the confirmation of a classical s</li> </ul>		No 999/2001, has been diagnosed or	
	- all animals in which classical scrapie	was confirmed have been killed and o	destroyed, and	
	<ul> <li>all goats and sheep on the holding had genotype and breeding ewes carrying</li> </ul>			
	<li>(iii) ovine and caprine animals, with the exc holding only if they come from a holding</li>			
Nc	tes			
Pa	rt I:			
_	Box reference I.6: Person responsible for the consignment in the E commodity; it may be filled in if the certificate is for import commo		I in only if it is a certificate for trans	
_	Box reference I.11: In case of consignments for the particular technonly.	nological studies or analyses: indicate	name and address of establishmen	
_	Box reference I.11 and I.12: Approval number: the registration numl authority.	ber of the establishment or plant, whic	h has been issued by the competer	
_	Box reference I.12: Place of destination: this box is to be filled in:			
	<ul> <li>products for the manufacture of derived products for uses outside in transit can only be stored in free zones, free warehouses and</li> </ul>		e for transit commodity. The product	
	- products for the particular technological studies or analyses: the	EU plant indicated in authorisation of c	competent authority when appropriate	
_	Box reference I.15: Registration number (railway wagons or contain case of unloading and reloading, the consignor must inform the BI		) or name (ship) is to be provided. I	
_	Box reference I.19: use the appropriate Harmonized System (HS)	code under the following headings: 05	5.11.91; 05.11.99 or 30.01.	
_	Box reference I.23: for bulk containers, the container number and t	the seal number (if applicable) should	be included.	
_	Box reference I.25: technical use: any use other than for animal co	onsumption.		
_	Box reference I.25: for the purposes of the certificate, 'technical us	e' includes use as a trade sample.		
_	Box reference I.26 and I.27: except for trade samples, which are certificate.	not sent in transit, fill in according to	o whether it is a transit or an impo	
_	Box reference I.28:			
	<ul> <li>products for the manufacture of derived products for uses outside of the approved establishment;</li> </ul>	e the feed chain: Manufacturing plant:	provide the veterinary control number	
	- products for the particular technological studies or analyses: the	EU plant indicated in authorisation of c	competent authority when appropriate	
	- Species: select from the following: Aves, Ruminantia, Mammalia	a - Ruminantia, Pesca, Mollusca, Crus	stacea, Invertebrata.	

COUNTRY	or for trade samples ( <sup>2</sup> )	or purposes outside the feed chain			
II. Health information	II.a. Certificate reference No	II.b.			
Part II:					
( <sup>1a</sup> ) OJ L 300, 14.11.2009, p. 1.					
( <sup>1b</sup> ) OJ L 54, 26.2.2011, p. 1.					
( <sup>2</sup> ) Delete as appropriate.					
( <sup>3</sup> ) The name and ISO code number of the exporting country as laid down in:					
— Part 1 of Annex II to Regulation (EU) No 206/2010,					
- the Annex to Regulation (EC) No 798/2008, and					
- the Annex to Regulation (EC) No 119/2009.					
In addition the ISO code of territories and parts thereof referred susceptible species concerned) should be included.	d to in Regulations mentioned in this	s footnote (where applicable for the			
( <sup>4</sup> ) Only for countries from where game meat intended for human cor European Union.	nsumption of the same animal species	is authorised for importation into the			
(5) Supplementary guarantees to be provided when the material of d African country or part thereof from where only maturated and deb for exportation to the European Union. The whole masseter muscle I, Part B(1) of Regulation (EC) No 854/2004 of the European Pari	oned fresh meat of domestic ruminants s of bovine animals, incised in accorda	s for human consumption is permitted ince with Annex I, Section IV, Chapter			
( <sup>6</sup> ) Only for certain South American countries.					
( <sup>7</sup> ) Only for certain South American and South African countries.					
( <sup>8</sup> ) OJ L 147, 31.5.2001, p. 1.					
( <sup>9</sup> ) OJ L 94, 1.4.2006, p. 28.					
— The signature and the stamp must be in a different colour to that ${f c}$	of the printing.				
<ul> <li>Note for the person responsible for the consignment in the European the consignment until it reaches the border inspection post.</li> </ul>	Union: this certificate is only for veteri	nary purposes and has to accompany			
Official veterinarian/Official inspector					
Name (in capital letters):	Qualifie	cation and title:			
Date:	Signati	ure:			
Stamp:					

### **CHAPTER 9**

## Health certificate

For fish oil not intended for human consumption to be used as feed material or for purposes outside the feed chain, intended for dispatch to or for transit through  $\binom{2}{1}$  the European Union

cou	NTRY	,							Veterinary certific	cate to EU
	l.1.	Consignor		1.2.	Certificate referen	nce No		1.2	2.a.	
		Name		1.3.	Central competer	nt autho	rity			
		Address					,			
		Tel.		1.4.	Local competent	authorit	у			
ŧ	1.5.	Consignee		1.6.	Person responsit	ole for ti	ne loa	d in E	U	
amu		Name			Name					
nsig		Address			Address					
CO CO		Postcode			Postcode					
dispatched consignment		Tel.			Tel.					
spat	1.7.	Country of origin ISO code I.8. Re	gion of origin Code	1.9.		IS		I.10.	Region of	Code
of di			1		destination	со 	de		destination	
I: Details o	I.11.	Place of origin		1.12.	Place of destinat	ion				
Det					Name			0.00	stom warehouse 🗌	
Part		Name Approval Address	number		Address				proval number	
		Name Approval Address	number		Postcode					
		Name Approval Address	number		1 OSICOUC					
	I.13.	Place of loading		I.14.	Date of departure	Э				
	l.15.	5. Means of transport			I.16. Entry BIP in EU					
			ailway wagon 🔲							
		Road vehicle Other I Identification		1.17.						
		Documentation references								
	I.18.	Description of commodity			I.19. C	ommodi	ty cod	e (HS	i code)	
							1.20. 0	Quanti	ity	
	I.21.	Temperature of product					1.22. 1	Numb	er of packages	
		Ambient Chilled		Froze	n 🗖					
	1.23.	Seal/Container No					1.24. 1	Гуре о	of packaging	
	1.25.	Commodities certified for:								
		Animal feedingstuff								
	1.26.	For transit through EU to third country		1.27.	For import or ad	mission	into E	U		ן נ
		Third country ISO code	9							
	1.28.	Identification of the commodities								
			nber of establishments Ifacturing plant	I	Number of packag	es	٢	vet we	eight Batch	number

cou	INTRY				Fish oil not intended for human c material or for purposes outside th		
	П.	Health inf	orma	ation	II.a. Certificate reference No	II.b.	
		and of the	Cou	ned official veterinarian, declare that I have read an ncil ( $^{1a}$ ) and in particular Article 10 thereof, and Coeof, and certify that the fish oil described above:			
	II.1.	consists of	fish	oil that satisfies the health requirements below;			
tion	II.2.	contains ex	kclus	ively fish oil not intended for human consumption	;		
Part II: Certification	II.3.			ared and stored in a dedicated fish plant approved, egulation (EC) No 1069/2009;	validated and supervised by the com	petent authority in accordance with	
art II:	II.4.	has been prepared exclusively with the following animal by-products:					
P		( <sup>2</sup> ) either [- animal by-products arising from the production of products intended for human consumption;]					
		( <sup>2</sup> ) and/or [- products of animal origin, or foodstuffs containing products of animal origin, which are no longer intended for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arise;]					
		( <sup>2</sup> ) and/or [- aquatic animals, and parts of such animals, except sea mammals, which did not show any signs of diseases commu- nicable to humans or animals;]					
		( <sup>2</sup> ) and/or [- animal by-products from aquatic animals originating from plants or establishments manufacturing products for human consumption;]					
	II.5.	the fish oil:					
			(a)	has been subjected to processing in accordance order to kill pathogenic agents;	with Annex X, Chapter II, Section 3 c	of Regulation (EU) No 142/2011, in	
			(b)	has not been in contact with other types of oil	s including rendered fats from any s	species of terrestrial animals, and	
		( <sup>2</sup> ) either	( <sup>2</sup> ) either [(c) is packaged in new containers or in containers that have been cleaned and disinfected if necessary for the prevention of contamination and all precautions taken to prevent their contamination,]				
		( <sup>2</sup> ) or	[(c)	where bulk transport is intended, the pipe, pumps the transportation of the product from the manufac plants have been inspected and found to be cle	cturing plant either directly on to the sh		
		and	(d)	which bear labels indicating 'NOT FOR HUMAN	CONSUMPTION'.		
	Notes Part I:						
				erson responsible for the consignment in the Euro e filled in if the certificate is for import commodity		n only if it is a certificate for transit	
				Place of destination: this box is to be filled in only nes, free warehouses and custom warehouses.	if it is a certificate for transit commodi	ty. The products in transit can only	
				Registration number (railway wagons or container unloading and reloading.	and lorries), flight number (aircraft) o	r name (ship); information is to be	
	— Вох	reference I	.19: 1	use the appropriate HS code: 15.04 or 15.18.			
	— Вох	reference I	.23: 1	for bulk containers, the container number and the	seal number (if applicable) should b	e included.	
	— Box	reference I	.25: 1	technical use: any use other than for animal cons	umption.		
	— Вох	reference I	.26 a	and I.27: fill in according to whether it is a transit	or an import certificate.		
	— Box	reference I	28:	Manufacturing plant: provide the registration numb	per of the treatment/processing establ	ishment.	

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011. (See end of Document for details)

COUNTRY	Fish oil not intended for human c material or for purposes outside th							
II. Health information	II.a. Certificate reference No	II.b.						
Part II:								
( <sup>1a</sup> ) OJ L 300, 14.11.2009, p. 1.								
( <sup>1b</sup> ) OJ L 54, 26.2.2011, p. 1.								
( <sup>2</sup> ) Delete as appropriate.								
- The signature and the stamp must be in a different colour to that of	the printing.							
<ul> <li>Note for the person responsible for the consignment in the Europ accompany the consignment until it reaches the border inspection p</li> </ul>		r veterinary purposes and has to						
Official veterinarian/Official inspector								
Name (in capital letters):	Qualification and	d title:						
Date:	Signature:							
Stamp:								

# CHAPTER 10(A)

## Health certificate

For rendered fats not intended for human consumption to be used as feed material, intended for dispatch to or for transit through  $(^2)$  the European Union

cou	NTR	(	Veterinary certificate to EU				
	l.1.	Consignor Name Address	I.2. Certificate reference No     I.2.a.       I.3. Central competent authority				
		Tel.	I.4. Local competent authority				
dispatched consignment	1.5.	Consignee Name Address Postcode Tel.	I.6. Person responsible for the load in EU Name Address Postcode Tel.				
of dispatc	1.7.	Country of origin ISO code I.8. Region of origin Code	I.9. Country of ISO destination Code destination				
etails	l.11.	Place of origin	I.12. Place of destination				
Part I: Details of		Name Approval number Address	Name Custom warehouse Address Approval number				
		Name Approval number Address Name Approval number	Postcode				
	1.10	Address					
	1.13.	Place of loading	I.14. Date of departure				
	l.15.	Means of transport	I.16. Entry BIP in EU				
		Aeroplane Ship Railway wagon I Road vehicle Other I Identification	l.17.				
	l.18.	Description of commodity	I.19. Commodity code (HS code)				
			I.20. Quantity				
	I.21.	Temperature of product Ambient Chilled	I.22. Number of packages				
	1.23.	Seal/Container No	I.24. Type of packaging				
	1.25.	Commodities certified for:					
		Animal feedingstuff	1				
	I.26.	For transit through EU to third country	I.27. For import or admission into EU				
	1.28.	Identification of the commodities	1				
		Species Nature of commodity Approval number of (Scientific name) Manufacturing					

соц	INTRY			Rendered fats not intended for hu feed material	man consumption to be used as				
	П.	Health inform	nation	II.a. Certificate reference No	II.b.				
		I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 of the European Parliament and of the Council ( <sup>1a</sup> ) and in particular Article 10 thereof, and Commission Regulation (EU) No 142/2011 ( <sup>1b</sup> ), and in particular Annex XIV, Chapter II thereof, and certify that the rendered fats described above:							
	II.1.	consist of ren	dered fats that satisfy the health requirements be	low;					
tion	11.2.	consist of ren	dered fats not intended for human consumption;						
Part II: Certification	II.3.	Regulation (E	epared and stored in a plant approved, validated a C) No 1069/2009 or in accordance with Article 4(2 order to kill pathogenic agents;						
Part I	II.4.	have been pr	have been prepared exclusively with the following animal by-products:						
			carcases and parts of animals slaughtered or, in t numan consumption in accordance with Union le reasons;]						
			carcases and the following parts originating either considered fit for slaughter for human consumption animals from game killed for human consumption	n following an ante-mortem inspection of					
			<ul> <li>carcases or bodies and parts of animals whic legislation, but which did not show any signs</li> </ul>						
			(ii) heads of poultry;						
		(	<li>iii) hides and skins, including trimmings and split metacarpus bones, tarsus and metatarsus bor</li>						
		(	iv) pig bristles;						
			(v) feathers;]						
			plood of animals which did not show any signs of o animals other than ruminants that have been slaug or human consumption following an ante-mortem	ghtered in a slaughterhouse after havin	g been considered fit for slaughter				
			animal by-products arising from the production of greaves and centrifuge or separator sludge from r		mption, including degreased bone,				
			products of animal origin, or foodstuffs containin consumption for commercial reasons or due to which no risk to public or animal health arise;]						
		i i	betfood and feedingstuffs of animal origin, or feed onger intended for feeding for commercial reaso defects from which no risk to public or animal hea	ons or due to problems of manufactur					
			blood, placenta, wool, feathers, hair, horns, hoof c any disease communicable through that product to		animals that did not show signs of				
			aquatic animals, and parts of such animals, except to humans or animals;]	t sea mammals, which did not show ar	ny signs of diseases communicable				
			animal by-products from aquatic animals origina consumption;]	ting from plants or establishments n	nanufacturing products for human				
			he following material originating from animals which to humans or animals:	ch did not show any signs of disease o	communicable through that material				
		(	i) shells from shellfish with soft tissue or flesh;						

COUN	TRY	Rendered fats not intended for human consumption to be used as feed material
П.	Health info	prmation II.a. Certificate reference No II.b.
		(ii) the following originating from terrestrial animals:
		— hatchery by-products,
		— eggs,
		<ul> <li>egg by-products, including egg shells;</li> </ul>
		(iii) day-old chicks killed for commercial reasons;]
11.5.	( <sup>2</sup> ) either	[- in the case of material of porcine origin, come from a country or part of a territory free from foot-and-mouth disease for the previous 24 months and free from classical swine fever and African swine fever for the previous 12 months;]
	( <sup>2</sup> ) and/or	[- in the case of material of poultry origin, come from a country or part of a territory free from Newcastle disease and avian influenza for the previous 6 months;]
	(²) and/or	[- in the case of material of ruminant origin, come from a country or part of a territory free from foot-and-mouth disease for the previous 24 months and free from rinderpest for the previous 12 months;]
	( <sup>2</sup> ) and/or	[- where there has been an outbreak of one of the abovementioned diseases during the relevant period mentioned above, and where the rendered fats are derived from a susceptible species, have been subjected to a heat treatment for at least 70 °C for 30 minutes or at least 90 °C for at least 15 minutes, and
		details of the critical control points are recorded and maintained so that the owner, operator or their representative and, as necessary, the competent authority can monitor the operation of the plant; the information must include the particle size, critical temperature and, as appropriate, the absolute time, pressure profile, raw material feed rate and fat recycling rate.]
II.6.	if derived f 0,15 % in	rom ruminant animals were purified in such way that the maximum levels of remaining total insoluble impurities does not exceed weight;
11.7.	the render	ad fats:
		(a) have been subjected to processing in accordance with Annex X, Chapter II, Section 3 of Regulation (EU) No 142/2011, or treatment in accordance with Section XII of Annex III to Regulation (EC) No 853/2004, in order to kill pathogenic agents; and
	( <sup>2</sup> ) either	[(b) are packaged in new containers or in containers that have been cleaned and disinfected if necessary for the prevention of contamination, and all precautions taken to prevent their contamination;]
	( <sup>2</sup> ) or	[(b) where bulk transport is intended, the pipe, pumps and bulk tanks and any other bulk container or bulk road tanker used in the transportation of the product from the manufacturing plant either directly on to the ship or into shore tanks or directly to plants have been checked under the responsibility of the competent authority and found to be clean before use;]
	and which	bear labels indicating 'NOT FOR HUMAN CONSUMPTION';
II.8.		
	( <sup>2</sup> ) either	[the product does not contain and is not derived from specified risk material as defined in Annex V to Regulation (EC) No 999/2001 of the European Parliament and of the Council ( <sup>4</sup> ) or mechanically separated meat obtained from bones of bovine, ovine or caprine animals; and the animals from which this product is derived have not been slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity;]
	( <sup>2</sup> ) or	[the product does not contain and is not derived from bovine, ovine or caprine materials other than those derived from animals born, continuously reared and slaughtered in a country or region classified as posing a negligible BSE risk by a decision in accordance with Article 5(2) of Regulation (EC) No 999/2001;]
11.9.	in addition	as regards TSE:
	( <sup>2</sup> ) either	[in case of animal by-products intended for feeding ruminants and containing milk or milk products of ovine or caprine origin, the ovine and caprine animals from which these products are derived have been kept continuously since birth or for the last three years on a holding where no official movement restriction is imposed due to a suspicion of TSE and which has satisfied the following requirements for the last three years:
		(i) it has been subject to regular official veterinary checks;

COUNT	TRY	Rendered fats not intended for human consumption to be used as feed material
П.	Health info	prmation II.a. Certificate reference No II.b.
		<ul> <li>(ii) no classical scrapie case, as defined in point 2(g) of Annex I to Regulation (EC) No 999/2001, has been diagnosed or, following the confirmation of a classical scrapie case:</li> </ul>
		- all animals in which classical scrapie was confirmed have been killed and destroyed, and
		<ul> <li>— all goats and sheep on the holding have been killed and destroyed, except for breeding rams of the ARR/ARR genotype and breeding ewes carrying at least one ARR allele and no VRQ allele;</li> </ul>
		(iii) ovine and caprine animals, with the exception of sheep of the ARR/ARR prion genotype, are introduced into the holding only if they come from a holding which complies with the requirements set out in points (i) and (ii).]
	( <sup>2</sup> ) or	[in case of animal by-products intended for feeding ruminants and containing milk or milk products of ovine or caprine origin, and destined to a Member State listed in the Annex to Commission Regulation (EC) No 546/2006 <sup>(5)</sup> , the ovine and caprine animals from which these products are derived have been kept continuously since birth or for the last seven years on a holding where no official movement restriction is imposed due to a suspicion of TSE and which has satisfied the following requirements for the last seven years:
		(i) it has been subject to regular official veterinary checks;
		<ul> <li>(ii) no classical scrapie case, as defined in point 2(g) of Annex I to Regulation (EC) No 999/2001, has been diagnosed or, following the confirmation of a classical scrapie case:</li> </ul>
		- all animals in which classical scrapie was confirmed have been killed and destroyed, and
		<ul> <li>— all goats and sheep on the holding have been killed and destroyed, except for breeding rams of the ARR/ARR genotype and breeding ewes carrying at least one ARR allele and no VRQ allele;</li> </ul>
		(iii) ovine and caprine animals, with the exception of sheep of the ARR/ARR prion genotype, are introduced into the holding only if they come from a holding which complies with the requirements set out in points (i) and (ii).]
Notes		
Part I	:	
		6: Person responsible for the consignment in the European Union: this box is to be filled in only if it is a certificate for transit ay be filled in if the certificate is for import commodity.
		12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only a zones, free warehouses and custom warehouses.
		15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be a of unloading and reloading.
— Во	x reference I.	19: use the appropriate HS code: 15.02; 15.03; 15.04; 15.05; 15.06; 15.16.10; 15.17 or 15.18.
— Во	x reference I.2	23: for bulk containers, the container number and the seal number (if applicable) should be included.
— Во	x reference I.2	25: technical use: any use other than for animal consumption.
— Во	x reference I.2	26 and I.27: fill in according to whether it is a transit or an import certificate.
— Во	x reference I.2	28: Manufacturing plant: provide the registration number of the treatment/processing establishment.
Part I	:	
( <sup>1a</sup> ) C	J L 300, 14.1	11.2009, p. 1.
( <sup>1b</sup> ) C	J L 54, 26.2.	2011, p. 1.
(2) 🛛	elete as appr	ropriate.
( <sup>3</sup> ) C	J L 139, 30.4	4.2004, p. 55.

	Rendered fats not intended for hu feed material	man consumption to be used as					
II. Health information	II.a. Certificate reference No	II.b.					
( <sup>4</sup> ) OJ L 147, 31.5.2001, p. 1.							
( <sup>5</sup> ) OJ L 94, 1.4.2006, p. 28.							
- The signature and the stamp must be in a different colour to that of	the printing.						
<ul> <li>Note for the person responsible for the consignment in the Europ accompany the consignment until it reaches the border inspection p</li> </ul>		or veterinary purposes and has to					
Official veterinarian/Official inspector							
Name (in capital letters):	Qualification a	nd title:					
Date:	Signature:						
Stamp:							

# [<sup>F1</sup>CHAPTER 10(B)

### Health certificate

For rendered fats not intended for human consumption to be used for certain purposes outside the feed chain, intended for dispatch to or for transit through  $\binom{2}{1}$  the European Union]

cou	NTR	r							Veterinary ce	rtificate to EU
	l.1.	Consignor				1.2.	Certifica	te reference No	I.2.a.	
		Name								
		Address				I.3. Central competent authority				
		Tel.				1.4.	Local co	ompetent authority		
ent	1.5.	Consignee				1.6.	Person	responsible for the lo	ad in EU	
E		Name					Name			
Isig		Address					Address	1		
ō		Postcode					Postcod	e		
hed		Tel.					Tel.			
Part I: Details of dispatched consignment	1.7.	Country of origin	ISO code	I.8. Region of origin	Code	1.9.	Country destinat		I.10. Region of destination	Code
ď										
tails	I.11.	Place of origin				I.12.	Place of	f destination		
l: De		Name Address		Approval numb	er		Name Address		stom warehouse 🗌 proval number	
Part		Name Address		Approval numb	ber		Postcod			
		Name Address		Approval numb	er					
	I.13.	B. Place of loading				l.14.	Date of	departure		
	l.15.	5. Means of transport				I.16. Entry BIP in EU				
		Aeroplane 🗌	Ship	Railway w	/agon 🔲					
		Road vehicle 🗌	Othe			<u> </u>				
		Identification				1.17.				
		Documentation refe	erences							
	l.18.	Description of com	modity					I.19. Commodity co	de (HS code)	
									I.20. Quantity	
	I.21.	Temperature of pro	oduct						I.22. Number of pack	ages
		Ambient 🗌		Chilled				Frozen		
	1.23.	Seal/Container No							I.24. Type of packag	ing
	1.25.	Commodities certif	ied for:							
		Technical use								
	I.26.	For transit through	EU to third of	ountry [		1.27.	For impo	rt or admission into E	EU	
		Third country		ISO code						
	1.28.	Identification of the	commodities	;						
		Species	Approva	I number of establishmen	nts Nu	mber (	of packag	jes Net we	eiaht Bi	atch number

ou	NTRY		Rendered fats not intended for human consumption for cer purposes outside the feed chain							
	П.	Health info	tion II.a. Certificate reference No II.b.							
		and of the C	ed official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 of the European Parliam cil ( <sup>1a</sup> ) and in particular Articles 8, 9 and 10 thereof, and Regulation (EU) No 142/2011 ( <sup>1b</sup> ), and in particular Annex X of, and certify that the rendered fats described above:							
	II.1.	consist of re	red fats not intended for human consumption that satisfy the health requirements below;							
	II.2.	have been p	ave been prepared exclusively with the following animal by-products:							
	II.2.1.		n the case of materials destined for the production of biodiesel or oleochemical products, animal by-products referred to in Articles 8, 9 ind 10 of Regulation (EC) No 1069/2009;							
Ĩ	II.2.2.		naterials destined for the production of renewable fuels referred to in point J of Section 2 of Chapter IV of Annex IV No 142/2011, animal by-products referred to in Articles 9 and 10 of Regulation (EC) No 1069/2009;							
	II.2.3.	in the case	naterials destined for purposes other than cosmetics, pharmaceuticals or medical devices:							
_		(²) either	animal by-products containing residues of authorised substances or contaminants exceeding the permitted levels reference to in Article 15(3) of Directive 96/23/EC;]							
		(²) and/or	products of animal origin which have been declared unfit for human consumption due to the presence of foreign bodies those products;]							
		(²) and/or	animals and parts of animals, other than those referred to in Articles 8 and 10 of Regulation (EC) No 1069/2009, that d other than being slaughtered or killed for human consumption, including animals killed for disease control purpose							
		(²) and/or	carcases and parts of animals slaughtered or, in the case of game, bodies or parts of animals killed, and which are fit human consumption in accordance with Union legislation, but are not intended for human consumption for commer reasons;]							
		(²) and/or	carcases and the following parts originating either from animals that have been slaughtered in a slaughterhouse and we considered fit for slaughter for human consumption following an ante-mortem inspection or bodies and the following part of animals from game killed for human consumption in accordance with Union legislation:							
			<ul> <li>(i) carcases or bodies and parts of animals which are rejected as unfit for human consumption in accordance with Un legislation, but which did not show any signs of disease communicable to humans or animals;</li> </ul>							
			(ii) heads of poultry;							
			<li>(iii) hides and skins, including trimmings and splitting thereof, horns and feet, including the phalanges and the carpus a metacarpus bones, tarsus and metatarsus bones;</li>							
			(iv) pig bristles;							
			(v) feathers;]							
		(²) and/or	blood of animals which did not show any signs of disease communicable through blood to humans or animals obtair from animals other than ruminants that have been slaughtered in a slaughterhouse after having been considered fit slaughter for human consumption following an ante-mortem inspection in accordance with Union legislation;]							
		(²) and/or	animal by-products arising from the production of products intended for human consumption, including degreased bo greaves and centrifuge or separator sludge from milk processing;]							
		(²) and/or	products of animal origin, or foodstuffs containing products of animal origin, which are no longer intended for hum consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects fr which no risk to public or animal health arises;]							
		(²) and/or	petfood and feeding stuffs of animal origin, or feeding stuffs containing animal by-products or derived products, which is no longer intended for feeding for commercial reasons or due to problems of manufacturing or packaging defects or ot defects from which no risk to public or animal health arises;]							
		(²) and/or	blood, placenta, wool, feathers, hair, horns, hoof cuts and raw milk originating from live animals that did not show signs any disease communicable through that product to humans or animals;]							
		(²) and/or	aquatic animals, and parts of such animals, except sea mammals, which did not show any signs of diseas communicable to humans or animals;]							
		(²) and/or	animal by-products from aquatic animals originating from plants or establishments manufacturing products for hum consumption;]							

COUNT	RY	Rendered fats not intended for human consumption for certain purposes outside the feed chain
Ш.	Health info	
	( <sup>2</sup> ) and/or	[- the following material originating from animals which did not show any signs of disease communicable through that material to humans or animals:
		(i) shells from shellfish with soft tissue or flesh;
		(ii) the following originating from terrestrial animals:
		— hatchery by-products,
		— eggs,
		<ul> <li>egg by-products, including egg shells;</li> </ul>
		(iii) day-old chicks killed for commercial reasons;]
	(²) and/or	[- aquatic and terrestrial invertebrates other than species pathogenic to humans or animals;]
	( <sup>2</sup> ) and/or	[- animals and parts thereof of the zoological orders of Rodentia and Lagomorpha, except Category 1 material as referred to in Article 8(a)(iii), (iv) and (v) of Regulation (EC) No 1069/2009and Category 2 material as referred to in Article 9(a) to (g) of that Regulation;]
	(²) and/or	[- hides and skins, hooves, feathers, wool, horns, hair and fur originating from dead animals that did not show any signs of disease communicable through that product to humans or animals;]
	(²) and/or	[- adipose tissue from animals which did not show any signs of disease communicable through that material to humans or animals, which were slaughtered in a slaughterhouse and which were considered fit for slaughter for human consumption following an ante-mortern inspection in accordance with Union legislation;]
II.2.4.		of materials destined for purposes other than the production of organic fertilisers or soil improvers, cosmetics, pharmaceutical devices or renewable fuels referred to in point J of Section 2 of Chapter IV of Annex IV to Regulation (EU) No 142/2011:
	(²) either	[- specified risk material as defined in Article 3(1)(g) of Regulation (EC) No 999/2001 of the European Parliament and of the Council ( <sup>3</sup> );]
	(²) and/or	[- entire bodies or parts of dead animals containing specified risk material as defined in Article 3(1)(g) of Regulation (EC) No 999/2001 at the time of disposal;]
	(²) and/or	<ul> <li>animal by-products which have been derived from animals which have been submitted to illegal treatment as defined in Article 1(2)(d) of Directive 96/22/EC or Article 2(b) of Directive 96/23/EC;]</li> </ul>
	(²) and/or	[- animal by-products containing residues of other substances and environmental contaminants listed in Group B(3) of Annex I to Directive 96/23/EC, if such residues exceed the permitted levels laid down by Union legislation or, in the absence thereof, by legislation of the Member State of importation;]
11.3.	the rendere	d fats:
		en subjected to processing in accordance with method as laid down in Chapter III of Annex IV to Regulation 142/2011, in order to kill pathogenic agents,
		een marked before shipment to the European Union with glyceroltriheptanoate (GTH), so that a homogenous minimum ation of at least 250 mg GTH per kilogram fat is achieved,
	(c) in the ca	ase of rendered fats of ruminant origin, insoluble impurities in excess of 0.15% in weight have been removed,
	(d) have be	en transported under conditions which prevent their contamination, and
	(e) bear lab	els on the packaging or container indicating "NOT FOR HUMAN OR ANIMAL CONSUMPTION";

# $\blacktriangleright^{^{(0)}}$ Rendered fats not intended for human consumption for certain purposes outside the feed chain $\blacktriangleleft$

COUNTRY			outside the feed chain		
11.	Health info	rmation	II.a. Certificate reference No	II.b.	
11.4.		of materials destined for organic fertilisers, cosmet n point J of Section 2 of Chapter IV of Annex IV to		, soil improvers or renewable fuels	
	( <sup>2</sup> ) either [the product does not contain and is not derived from specified risk material as defined in Annex V to Regulation (EC) Not 999/2001 or mechanically separated meat obtained from bones of bovine, ovine or caprine animals; and the animals from which this product is derived have not been slaughtered after stunning by means of gas injected into the cranial cavity o killed by the same method or slaughtered by laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity.]				
	( <sup>2</sup> ) or [the product does not contain and is not derived from bovine, ovine or caprine materials other than those derived from animals born, continuously reared and slaughtered in a country or region classified as posing a negligible BSE risk by a decision in accordance with Article 5(2) of Regulation (EC) No 999/2001.]				
Notes					
Part I:	:				
		Person responsible for the consignment in EU: this tificate is for import commodity.	box is to be filled in only if it is a certifie	cate for transit commodity; it may be	
	x reference I.1 thority.	1 and I.12: Approval number: the registration number	er of the establishment or plant, which	has been issued by the competent	
		2: Place of destination: this box is to be filled in only zones, free warehouses and custom warehouses.	if it is a certificate for a transit commo	dity. The products in transit can only	
		5: Registration number (railway wagons or containe g and reloading, the consignor must inform the BIP		or name (ship) is to be provided. In	
	x I.19: use the .17 or 15.18.	appropriate Harmonized System (HS) code under	the following headings: 15.01, 15.02;	15.03; 15.04; 15.05; 15.06; 15.16;	
— Bo	x reference I.2	3: for bulk containers, the container number and the	e seal number (if applicable) should b	e included.	
— Bo	x reference I.2	5: technical use: any use other than for animal con	sumption.		
— Bo	x reference I.2	6 and I.27: fill in according to whether it is a transit	t or an import certificate.		
— Bo	x reference I.2	8:			
— Sp	ecies: select fr	rom the following: Ruminantia, Other			
— Ма	anufacturing pla	ant: provide the registration number of the treatment	t/processing establishment.		
Part II	l:				
( <sup>1a</sup> ) O	J L 300, 14.11	.2009, p. 1.			
( <sup>1b</sup> ) O	J L 54, 26.2.2	011, p. 1.			
(²) De	elete as appro	priate.			
( <sup>3</sup> ) O	J L 147, 31.5.	2001, p. 1.			
— The	- The signature and the stamp must be in a different colour to that of the printing.				
	- Note for the person responsible for the consignment in EU: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.				
Officia	I veterinarian/C	Official inspector			
Na	me (in capital	letters):	Qualifica	tion and title:	
Da	te:		Signatur	e:	
Sta	amp:				

# [<sup>F1</sup>CHAPTER 11

### Health certificate

For gelatine and collagen not intended for human consumption to be used as feed material or for purposes outside the feed chain, intended for dispatch to or for transit through  $(^2)$  the European Union]

cou	COUNTRY Veterinary certificate to EU						
	l.1.	Consignor	I.2. Certificate reference No I.2.a.				
		Name					
		Address	I.3. Central competent authority				
		Tel.	I.4. Local competent authority				
ent	1.5.	Consignee	I.6. Person responsible for the load in EU				
mu		Name	Name				
nsig		Address	Address				
ō		Postcode	Postcode				
dispatched consignment		Tel.	Tel.				
spato	1.7.	Country of origin ISO code I.8. Region of origin Code	I.9. Country of ISO code I.10. Region of Code				
of dis			destination destination				
ils o	1.11.	Place of origin	I.12. Place of destination				
Deta		Name Approval number	Name Custom warehouse				
		Address	Address Approval number				
Part I: Details		Name Approval number Address	Postcode				
		Name Approval number Address					
	I.13.	Place of loading	I.14. Date of departure				
	l.15.	Means of transport	I.16. Entry BIP in EU				
		Aeroplane Ship Railway wagon					
		Road vehicle					
		Identification	l.17.				
		Documentation references					
	l.18.	Description of commodity	I.19. Commodity code (HS code)				
			I.20. Quantity				
	1.21.	Temperature of product	I.22. Number of packages				
		Ambient Chilled	Frozen				
	1.23.	Seal/Container No	I.24. Type of packaging				
	1.25.	Commodities certified for:					
		Animal feedingstuff Technical u	use 🗌				
	1.26.	For transit through EU to third country	I.27. For import or admission into EU				
		Third country ISO code					
	1.28.	Identification of the commodities					
		Species Approval number of establishments (Scientific name) Manufacturing plant	Number of packages Net weight Batch number				

OUN	TRY			Gelatine and collagen not intended for human consumption to used as feed material or for purposes outside the feed chain					
11		Health info	ormatio						
		and of the C	Council	official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 of the European Parliamer ( <sup>1a</sup> ) and in particular Article 10 thereof, and Commission Regulation (EU) No 142/2011 ( <sup>1b</sup> ), and in particular Chapter I of , and certify that the gelatine/collagen ( <sup>2</sup> ) described above:					
II II	.1.	consists of gelatine/collagen (2) that satisfy the health requirements below;							
II: Certification	1.2.	consist exclusively of gelatine/collagen ( <sup>2</sup> ) not intended for human consumption;							
Part II: Ce	1.3.	has been prepared and stored in a plant approved, validated and supervised by the competent authority in accordance with Article 24 of Regulation (EC) No 1069/2009, in order to kill pathogenic agents;							
	l.4.	has been prepared exclusively with the following animal by-products:							
		(²) either	hun	cases and parts of animals slaughtered or, in the case of game, bodies or parts of animals killed, and which are fit for man consumption in accordance with Union legislation, but are not intended for human consumption for commercia isons;]					
considered fit for slaughter for human consumption for				cases and the following parts originating either from animals that have been slaughtered in a slaughterhouse and wer nsidered fit for slaughter for human consumption following an ante-mortem inspection or bodies and the following parts of mals from game killed for human consumption in accordance with Union legislation:					
			(i)	) carcases or bodies and parts of animals which are rejected as unfit for human consumption in accordance with Unio legislation, but which did not show any signs of disease communicable to humans or animals;					
			) heads of poultry;						
<ul> <li>(iii) hides and skins, including trimmings and splitting thereof, horns and feet, including the phalanges and t metacarpus bones, tarsus and metatarsus bones;</li> <li>(iv) pig bristles;</li> <li>(v) feathers;]</li> </ul>									
							(²) and/or	mal by-products arising from the production of products intended for human consumption, including degreased bone vaves and centrifuge or separator sludge from milk processing;]	
									ducts of animal origin, or foodstuffs containing products of animal origin, which are no longer intended for huma nsumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects fror ich no risk to public or animal health arises:]
( <sup>2</sup> ) and/or [- petfood and feedingstuffs of animal origin, or feedingstuffs containing animal by-products or derived produce longer intended for feeding for commercial reasons or due to problems of manufacturing or packaging defects from which no risk to public or animal health arises;]									
		(²) and/or		uatic animals, and parts of such animals, except sea mammals, which did not show any signs of diseases communicabl humans or animals;]					
		(²) and/or		mal by-products from aquatic animals originating from plants or establishments manufacturing products for huma nsumption;]					
II.5. the gelatine/collagen ( <sup>2</sup> ):				en ( <sup>2</sup> ):					
			(a)	was wrapped, packaged, stored and transported under satisfactory hygiene conditions, and in particular wrapping an packaging took place in a dedicated room, and only preservatives permitted under Union legislation were used Wrappings and packages containing gelatine/collagen ( <sup>2</sup> ) carry the words "GELATINE/COLLAGEN ( <sup>2</sup> ) SUITABL FOR ANIMAL CONSUMPTION"; and					
		(²) either	[(b)	) in the case of gelatine, has been produced by a process that is ensuring that unprocessed Category 3 material i subjected to a treatment with acid or alkali, followed by one or more rinses, involving pH adjustment, extraction b heating one or several times in succession, followed by purification by means of filtration and sterilisation, in order t kill pathogenic agents;]					
		(²) or	[(b)	) in the case of collagen, has been produced by a process that ensuring that unprocessed Category 3 material i subjected to a treatment involving washing, pH adjustment using acid or alkali followed by one or more rinses, filtratio and extrusion, in order to kill pathogenic agents;]					

11.	Health info	rmation	II.a. Certificate reference No	II.b.	
II.6.		of gelatine/collagen ( <sup>2</sup> ) from materials other than			
	( <sup>2</sup> ) either [the product does not contain and is not derived from specified risk material as defined in Annex V to Regulation (EC) No 999/2001 of the European Parliament and of the Council ( <sup>3</sup> ) or mechanically separated meat obtained from bones of bovine, ovine or caprine animals; and the animals from which this product is derived have not been slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity.]				
	(²) or	[the product does not contain and is not deri animals born, continuously reared and slaugh decision in accordance with Article 5(2) of Re	tered in a country or region classified		
II.7.		of gelatine/collagen ( <sup>2</sup> ) from materials other than as regards TSE:	hides and skins:		
	(²) either	[in case of animal by-products intended for f origin, the ovine and caprine animals from whi the last three years on a holding where no of has satisfied the following requirements for th	ch these products are derived have be ficial movement restriction is imposed	een kept continuously since birth or fo	
		(i) it has been subject to regular official veter	rinary checks;		
		<ul> <li>(ii) no classical scrapie case, as defined in po following the confirmation of a classical so</li> </ul>		No 999/2001, has been diagnosed o	
		- all animals in which classical scrapie v	was confirmed have been killed and d	lestroyed, and	
		<ul> <li>all goats and sheep on the holding has genotype and breeding ewes carrying</li> </ul>			
		<li>(iii) ovine and caprine animals, with the except only if they come from a holding which co</li>			
	( <sup>2</sup> ) or	[in case of animal by-products intended for f origin, and destined to a Member State listed caprine animals from which these products are on a holding where no official movement res following requirements for the last seven year	in the Annex to Commission Regulatic e derived have been kept continuously triction is imposed due to a suspicio	n (EC) No 546/2006 ( <sup>4</sup> ), the ovine an since birth or for the last seven year	
		(i) it has been subject to regular official veter	rinary checks;		
		<ul> <li>(ii) no classical scrapie case, as defined in po following the confirmation of a classical so</li> </ul>		No 999/2001, has been diagnosed o	
		- all animals in which classical scrapie w	was confirmed have been killed and d	lestroyed, and	
		<ul> <li>all goats and sheep on the holding has genotype and breeding ewes carrying</li> </ul>			
		<ul> <li>(iii) ovine and caprine animals, with the except only if they come from a holding which come</li> </ul>			
Notes					
Part I	:				
	Box reference I.6: Person responsible for the consignment in the European Union: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.				
	lox reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only e stored in free zones, free warehouses and custom warehouses.				
	ex reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship) is to be provided. In se of unloading and reloading, the consignor must inform the BIP of entry into the EU.				
— Во	x I.19: use the	appropriate Harmonized System (HS) code und	er the following headings: 35.03 or 35	5.04.	
— Во	x reference 1.2	3: for bulk containers, the container number and	the seal number (if applicable) should	d be included.	
— Во	x reference I.2	5: technical use: any use other than for animal o	consumption.		
— Во	x reference I.2	6 and I.27: fill in according to whether it is a tran	nsit or an import certificate.		
— Во	x reference L2	8: Species: select from the following: Aves, Rum	inantia, Mammalia - Ruminantia, Peso	ca.	

COUNTRY	Gelatine and collagen not inte used as feed material or for pu	ended for human consumption to be urposes outside the feed chain
II. Health information	II.a. Certificate reference No	II.b.
Part II:		
( <sup>1a</sup> ) OJ L 300, 14.11.2009, p. 1.		
( <sup>1b</sup> ) OJ L 54, 26.2.2011, p. 1.		
( <sup>2</sup> ) Delete as appropriate.		
( <sup>3</sup> ) OJ L 147, 31.5.2001, p. 1.		
( <sup>4</sup> ) OJ L 94, 1.4.2006, p. 28.		
- The signature and the stamp must be in a different colour to that c	of the printing.	
<ul> <li>Note for the person responsible for the consignment in the European the consignment until it reaches the border inspection post.</li> </ul>	Union: this certificate is only for vet	erinary purposes and has to accompany
Official veterinarian/Official inspector		
Name (in capital letters):	Qua	ification and title:
Date:	Sign	ature:
Stamp:		

## CHAPTER 12

### Health certificate

For hydrolysed protein, dicalcium phosphate and tricalcium phosphate not intended for human consumption to be used as feed material or for uses outside the feed chain, intended for dispatch to or for transit through  $(^2)$  the European Union

cou	NTR	,	Veterinary certificate to EU			
	l.1.	Consignor	I.2. Certificate reference No I.2.a.			
		Name	I.3. Central competent authority			
		Address				
		Tel.	I.4. Local competent authority			
ŧ	1.5.	Consignee	I.6. Person responsible for the load in EU			
nme		Name	Name			
nsig		Address	Address			
ō		Postcode	Postcode			
dispatched consignment		Tel.	Tel.			
spat	1.7.	Country of origin ISO code I.8. Region of origin Code	I.9. Country of ISO I.10. Region of Code			
of di			destination code destination			
	l.11.	Place of origin	I.12. Place of destination			
Det						
Part I: Details		Name Approval number Address	Name Custom warehouse Address Approval number			
"		Name Approval number Address	Postcode			
		Name Approval number Address				
	I.13.	Place of loading	I.14. Date of departure			
	l.15.	Means of transport	I.16. Entry BIP in EU			
		Aeroplane 🗌 Ship 🗌 Railway wagon 🗌				
		Road vehicle Other	1.17.			
		Identification				
		Documentation references				
	l.18.	Description of commodity	I.19. Commodity code (HS code)			
			I.20. Quantity			
	I.21.	Temperature of product	I.22. Number of packages			
		Ambient Chilled	Frozen			
	1.23.	Seal/Container No	I.24. Type of packaging			
	1.25.	Commodities certified for:	·			
		Animal feedingstuff Technical use				
	1.26.	For transit through EU to third country	I.27. For import or admission into EU			
		Third country ISO code				
	1.28.	Identification of the commodities				
		Species Nature of commodity Approval number of e (Scientific name) Manufacturing				

		Hydrolysed protein, dicalcium pho not intended for human consumpti- for uses outside the feed chain							
	П.	Health inf	orn	nation	II.a. Certificate reference No	II.b.			
		I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 of the Eur and of the Council ( <sup>1a</sup> ) and in particular Article 10 thereof, and Commission Regulation (EU) No 142/2011 ( <sup>1b</sup> ), and in part Chapter I thereof, and certify that the hydrolysed protein/dicalcium phosphate/tricalcium phosphate ( <sup>2</sup> ) described above:							
=	II.1.	consists of	f hy	drolysed protein/dicalcium phosphate/tricalcium ph	nosphate (²) that satisfy the health req	uirements below;			
ificatio	II.2.	consists e	xclu	sively of hydrolysed protein/dicalcium phosphate/t	ricalcium phosphate (2) not intended fo	or human consumption;			
Part II: Certification	II.3.	has been prepared and stored in a plant approved, validated and supervised by the competent authority in accordance with Article 24 of Regulation (EC) No 1069/2009, in order to kill pathogenic agents;							
Par	II.4.	has been	pre	pared exclusively with the following animal by-proc	ducts:				
	II.4.1.	in the case	e of	f dicalcium phosphate derived from defatted bones	S:				
				parts of animals slaughtered or, in the case of in accordance with Union legislation, but are not in					
	II.4.2.	in case of	oth	er materials:					
		( <sup>2</sup> ) either	[-	carcases and parts of animals slaughtered or, in human consumption in accordance with Union la reasons;]					
					er from animals that have been slaughtered in a slaughterhouse and were on following an ante-mortem inspection or bodies and the following parts of n in accordance with Union legislation:				
		<ul> <li>(i) carcases or bodies and parts of animals which are rejected as unfit for human consumption in accordance with Ur legislation, but which did not show any signs of disease communicable to humans or animals;</li> </ul>							
				(ii) heads of poultry;					
		<ul> <li>(iii) hides and skins, including trimmings and splitting thereof, horns and feet, including the phalanges and the carpus a metacarpus bones, tarsus and metatarsus bones, of animals, other than ruminants;</li> </ul>							
				(iv) pig bristles;					
		(v) feathers;]							
		( <sup>2</sup> ) and/or [- blood of animals which did not show any signs of disease communicable through blood to humans or animals obtaine animals other than ruminants that have been slaughtered in a slaughterhouse after having been considered fit for sla for human consumption following an ante-mortem inspection in accordance with Union legislation;]				ng been considered fit for slaughter			
		(²) and/or	[-	animal by-products arising from the production o greaves and centrifuge or separator sludge from		mption, including degreased bone,			
		( <sup>2</sup> ) and/or	[-	products of animal origin, or foodstuffs containin consumption for commercial reasons or due to which no risk to public or animal health arise;]					
		( <sup>2</sup> ) and/or	[-	petfood and feedingstuffs of animal origin, or feed longer intended for feeding for commercial reaso defects from which no risk to public or animal he	ons or due to problems of manufactu				
		(²) and/or	[-	blood, placenta, wool, feathers, hair, horns, hoof any disease communicable through that product the		animals that did not show signs of			

COUN	TRY			Hydrolysed protein, dicalcium pho not intended for human consumpt for uses outside the feed chain		
II.	Health inf	forma	tion	II.a. Certificate reference No	II.b.	
	(²) and/or		quatic animals, and parts of such animals, excep humans or animals;]	ot sea mammals, which did not show a	any signs of diseases communicable	
	(²) and/or		nimal by-products from aquatic animals origin onsumption;]	ating from plants or establishments	manufacturing products for human	
	(²) and/or	/or [- the following material originating from animals which did not show any signs of disease communicable through that mat to humans or animals:			communicable through that materia	
		(	(i) shells from shellfish with soft tissue or fiesh;			
	(ii) the following originating from terrestrial animals:					
			- hatchery by-products,			
			— eggs,			
			- egg by-products, including egg shells;			
		(ii	i) day-old chicks killed for commercial reasons;	:]		
II.5.	the hydroly	ysed	protein/dicalcium phosphate/tricalcium phosphat	e (²):		
		(a)	was wrapped and packaged in packaging which and transported under satisfactory hygiene con room, and only preservatives permitted under	ditions, and in particular wrapping and		
( <sup>2</sup> ) either [(b) in the case of hydrolysed protein, has been produced by a process involving appropriate measures to mination of raw Category 3 material.		riate measures to minimise contar				
			In the case of hydrolysed proteins entirely or processing plant dedicated only to hydrolysed Category 3 material by brining, liming and inte	proteins production, using a process		
			<ul> <li>(i) exposure of the material to a pH of more subsequently by heat treatment at more th</li> </ul>			
			<ul><li>(ii) exposure of the material to a pH of 1 to 2, f 30 minutes at 3 bar.]</li></ul>	followed by a pH of more than 11, follo	owed by heat treatment at 140 °C fo	
	( <sup>2</sup> ) or	[(b)	in the case of dicalcium phosphate, has been	produced by a process that:		
			<ul> <li>(i) ensures that all Category 3 bone material hydrochloric acid (at a minimum concentral</li> </ul>			
			<li>(ii) followed by treatment of the obtained phose pH 4 to 7, and</li>	phoric liquor with lime, resulting in a p	precipitate of dicalcium phosphate a	
			(iii) finally air-dries this precipitate, with inlet t 65 °C.]	emperature of 65 °C to 325 °C and e	nd temperature between 30 °C an	
	( <sup>2</sup> ) or	[(b)	in the case of tricalcium phosphate, has been	produced by a process ensuring:		
			<ul> <li>(i) that all Category 3 bone-material is finely c 14 mm),</li> </ul>	rushed and degreased in counter-flow	with hot water (bone chips less tha	
			(ii) continuous cooking with steam at 145 $^\circ\mathrm{C}$	during 30 minutes at 4 bars,		
			(iii) separation of the protein broth from the hy	ydroxyapatite (tricalcium phosphate) b	y centrifugation, and	
			(iv) granulation of the tricalcium phosphate aft	er drying in a fluidised bed with air at	t 200 °C.]	

COUN	TRY		Hydrolysed protein, dicalcium pho not intended for human consumpti for uses outside the feed chain			
П.	Health inf	ormation	II.a. Certificate reference No	II.b.		
II.6.	I.6. ( <sup>2</sup> ) either [the product does not contain and is not derived from specified risk material as defined in Annex V to Regulation (E No 999/2001 of the European Parliament and of the Council ( <sup>3</sup> ) or mechanically separated meat obtained from bones bovine, ovine or caprine animals; and the animals from which this product is derived have not been slaughtered at stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration					
	(²) or	central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity;] [the product does not contain and is not derived from bovine, ovine or caprine materials other than those derived from animals born, continuously reared and slaughtered in a country or region classified as posing a negligible BSE risk by a decision in accordance with Article 5(2) of Regulation (EC) No 999/2001;]				
11.7.	in addition	as regards TSE:				
	( <sup>2</sup> ) either	[in case of animal by-products intended for feeding the ovine and caprine animals from which these pro three years on a holding where no official movemen the following requirements for the last three years:	oducts are derived have been kept cor	tinuously since birth or for the last		
		(i) it has been subject to regular official veterinary	checks;			
		<ul> <li>(ii) no classical scrapie case, as defined in point 2 following the confirmation of a classical scrapie</li> </ul>		999/2001, has been diagnosed or,		
		- all animals in which classical scrapie was co	onfirmed have been killed and destroy	ed, and		
		<ul> <li>all goats and sheep on the holding have genotype and breeding ewes carrying at lea</li> </ul>				
		(iii) ovine and caprine animals, with the exception of only if they come from a holding which complie				
	(²) or	[in case of animal by-products intended for feeding and destined to a Member State listed in the Anney animals from which these products are derived have where no official movement restriction is imposed du for the last seven years:	K to Commission Regulation (EC) No 5 been kept continuously since birth or for the second	546/2006 ( <sup>4</sup> ), the ovine and caprine or the last seven years on a holding		
		(i) it has been subject to regular official veterinary	checks;			
		<ul> <li>(ii) no classical scrapie case, as defined in point 2 following the confirmation of a classical scrapie</li> </ul>		999/2001, has been diagnosed or,		
		— all animals in which classical scrapie was co	onfirmed have been killed and destroy	ed, and		
		<ul> <li>all goats and sheep on the holding have genotype and breeding ewes carrying at lea</li> </ul>				
		<li>(iii) ovine and caprine animals, with the exception c only if they come from a holding which complie</li>				
Notes	Notes					
Part I:						
	— Box reference I.6: Person responsible for the consignment in the European Union: this box is to be filled in only if it is a certificate for transi commodity; it may be filled in if the certificate is for import commodity.					
		.12: Place of destination: this box is to be filled in only e zones, free warehouses and custom warehouses.	/ if it is a certificate for transit commod	ity. The products in transit can only		
		.15: Registration number (railway wagons or containe e of unloading and reloading.	r and lorries), flight number (aircraft) o	or name (ship); information is to be		
— Во	x reference l	.19: use the appropriate HS code: 28.35 or 35.04.				
— Во	x reference l	.23: for bulk containers, the container number and th	e seal number (if applicable) should b	e included.		

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011. (See end of Document for details)

COUNTRY		hosphate and tricalcium phosphate ption to be used as feed material or
II. Health information	II.a. Certificate reference No	II.b.
- Box reference I.25: technical use: any use other than for animal	l consumption.	
- Box reference I.26 and I.27: fill in according to whether it is a tr	ransit or an import certificate.	
- Box reference I.28: Nature of commodity: specify if hydrolysed	protein, dicalcium phosphate or tricalciun	n phosphate.
Manufacturing plant: provide the registration number of treatmen	nt/processing establishment.	
Part II:		
( <sup>1a</sup> ) OJ L 300, 14.11.2009, p. 1.		
( <sup>1b</sup> ) OJ L 54, 26.2.2011, p. 1.		
( <sup>2</sup> ) Delete as appropriate.		
( <sup>3</sup> ) OJ L 147, 31.5.2001, p. 1.		
( <sup>4</sup> ) OJ L 94, 1.4.2006, p. 28.		
- The signature and the stamp must be in a different colour to the	at of the printing.	
<ul> <li>Note for the person responsible for the consignment in the E accompany the consignment until it reaches the border inspection</li> </ul>		for veterinary purposes and has to
Official veterinarian/Official inspector		
Name (in capital letters):	Qualification a	and title:
Date:	Signature:	
Stamp:		

### CHAPTER 13

### Health certificate

For apiculture by-products intended exclusively for use in apiculture, intended for dispatch to or for transit through  $\binom{2}{}$  the European Union

I.1. Consignor       I.2. Certificate reference No       I.2.a.         Name       Address       I.3. Central competent authority         Tel.       I.4. Local competent authority         I.5. Consignee       Name         Name       Address         Postcode       Postcode         Tel.       I.6. Person responsible for the load in EU         Name       Address         Postcode       Postcode         Tel.       I.1. Place of origin         I.1. Place of origin       I.2. Custory of get origin address         Name       Approval number         Address       Approval number         Name       Approval number         Address       Approval number         Name       Approval number         Address       Approval number         Name       Approval number         Address       Postcode         I.13. Place of loading       I.14. Date of departure         I.15. Means of transport       I.16. Entry BIP in EU         Road vehicle       Other       I.10. Commodity code (HS code)         I.18. Description of commodity       I.19. Commodity code (HS code)         I.18. Description of commodity       I.20. Quantity         I.21. Temperature of	te to EU		
Address       1.3. Central competent authority         Tel.       1.4. Local competent authority         1.5. Consignee       1.4. Local competent authority         Name       Address         Postcode       7el.         1.7. Country of origin       ISO code         1.1. Place of origin       I.12. Place of destination         1.11. Place of origin       I.12. Place of destination         Name       Approval number         Address       Approval number         Name       Approval number         Address       Approval number         Name       Approval number         Address       I.14. Date of departure         1.13. Place of loading       I.14. Date of departure         1.15. Means of transport       I.16. Entry BIP in EU         Acceptane [			
Address       I.4. Local competent authority         Tel.       I.4. Local competent authority         I.5. Consignee       Name         Address       I.6. Person responsible for the load in EU         Name       Address         Postcode       Fel.         I.7. Country of origin       ISO code         I.8. Region of origin       Code         I.1. Place of origin       I.8. Region of origin         Country of origin       I.9. Country of destination         Name       Approval number         Address       Approval number         Name       Approval number         Address       Approval number         Address       Approval number         Address       Approval number         Address       Approval number         Name       Approval number         Address       Approval number         I.13. Place of loading       I.14. Date of departure         I.15. Means of transport       I.16. Entry BIP in EU         Accountition       I.17.         Identification       I.19. Commodity code (HS code)         I.20. Quantity       I.20. Quantity         I.21. Temperature of product       I.22. Number of packages         Ambient	L3. Central competent authority		
Tel.       1.6.       Person responsible for the load in EU         Name       Address       Postcode         Postcode       Postcode       Tel.         1.7.       Country of origin       ISO code       1.8.       Postcode         Tel.       1.7.       Country of origin       ISO code       1.8.       Postcode         Tel.       1.7.       Country of origin       ISO code       1.8.       Region of origin         1.11.       Place of origin       ISO code       1.8.       Region of origin       Code         1.11.       Place of origin       I.12.       Place of destination       Name         Address       Approval number       Address       Approval number         Address       Approval number       Address       Approval number         Address       Approval number       Address       Approval number         I.13.       Place of loading       I.14.       Date of departure         I.15.       Means of transport       I.16.       EU         Read vehicle       Other       I.17.       I.19.       Commodity code (HS code)         I.18.       Description of commodity       I.19.       Commodity code (HS code)       I.20.         I.21.			
Name       Name         Address       Postcode         Tel.       Postcode         1.7. Country of origin       ISO code       1.8. Region of origin       Code         1.11. Place of origin       ISO code       I.12. Place of destination       ISO code         Name       Approval number       Address       Approval number         Address       Approval number       Address       Approval number         Name       Approval number       Address       Approval number         Name       Approval number       I.14. Date of departure       I.16. Entry BIP in EU         I.13. Place of loading       I.16. Entry BIP in EU       I.17.         Identification       Doumentation references       I.17.         I.18. Description of commodity       I.19. Commodity code (HS code)         I.19. Commodity code (HS code)       I.20. Quantity         I.21. Temperature of product       Prozen         I.22. Number of packages         Ambient         Chilled         Frozen         I.24. Type of packaging         I.25. Commodities certified for:       Technical use         I.24. Type of packaging			
Interview       Interview			
Interview       Interview			
b       I.11. Place of origin       I.12. Place of destination         I.11. Place of origin       I.12. Place of destination         Name       Approval number         Address       Approval number         Name       Approval number         Address       Postcode         Name       Approval number         Address       Postcode         I.13. Place of loading       I.14. Date of departure         I.15. Means of transport       I.16. Entry BIP in EU         Read vehicle       Other         I.18. Description of commodity       I.17.         I.18. Description of commodity       I.19. Commodity code (HS code)         I.20. Quantity       I.21. Temperature of product         Ambient       Chilled       Frozen         I.23. Seal/Container No       I.24. Type of packaging         I.25. Commodities certified for:       Technical use			
Interview       Interview			
Interview       Interview	Code		
Interpretation       Interpretation       Interpretation       Interpretation         Interpretation       Name       Approval number       Address       Custom warehouse and Approval number         Address       Name       Approval number       Address       Approval number         Address       Name       Approval number       Address       Approval number         Address       Name       Approval number       Postcode         Intal:       Place of loading       Interpretation       Postcode         Intal:       Place of loading       Interpretation       Interpretation         Intal:       Description of commodity       Interpretation       Interpretation         Interpretation       Interpretation       Interpretation       Interpretation         Interpretation       Interpretation       Interpretation       Interpretation         Interpretation       Interpretation       Interpretation       Interpretation         Interpretation       Interpretation       Interpretatio	Code		
Name       Approval number         Address       Approval number         Name       Approval number         Address       Postcode         1.13. Place of loading       I.14. Date of departure         I.15. Means of transport       I.16. Entry BiP in EU         Aeroplane       Ship         Road vehicle       Other         Identification       I.17.         Documentation references       I.19. Commodity code (HS code)         I.18. Description of commodity       I.19. Commodity code (HS code)         I.20. Quantity       I.20. Quantity         I.21. Temperature of product       I.22. Number of packages         Ambient       Chilled       Frozen         I.23. Seal/Container No       I.24. Type of packaging         I.25. Commodities certified for:       Technical use			
Name       Approval number         Address       Approval number         Name       Approval number         Address       Postcode         1.13. Place of loading       I.14. Date of departure         I.15. Means of transport       I.16. Entry BiP in EU         Aeroplane       Ship         Road vehicle       Other         Identification       I.17.         Documentation references       I.19. Commodity code (HS code)         I.18. Description of commodity       I.19. Commodity code (HS code)         I.20. Quantity       I.20. Quantity         I.21. Temperature of product       I.22. Number of packages         Ambient       Chilled       Frozen         I.23. Seal/Container No       I.24. Type of packaging         I.25. Commodities certified for:       Technical use			
Name       Approval number         Address       Approval number         Name       Approval number         Address       Postcode         1.13. Place of loading       I.14. Date of departure         I.15. Means of transport       I.16. Entry BiP in EU         Aeroplane       Ship         Road vehicle       Other         Identification       I.17.         Documentation references       I.19. Commodity code (HS code)         I.18. Description of commodity       I.19. Commodity code (HS code)         I.20. Quantity       I.20. Quantity         I.21. Temperature of product       I.22. Number of packages         Ambient       Chilled       Frozen         I.23. Seal/Container No       I.24. Type of packaging         I.25. Commodities certified for:       Technical use			
Name Address     Approval number       1.13. Place of loading     I.14. Date of departure       1.15. Means of transport     I.16. Entry BIP in EU       Aeroplane     Ship       Road vehicle     Other       Identification     I.17.       Documentation references     I.19. Commodity code (HS code)       I.18. Description of commodity     I.19. Commodity code (HS code)       I.20. Quantity     I.21. Temperature of product       Ambient     Chilled       I.23. Seal/Container No     I.24. Type of packaging       I.25. Commodities certified for:       Technical use			
I.13. Place of loading       I.14. Date of departure         I.13. Place of loading       I.14. Date of departure         I.15. Means of transport       I.16. Entry BIP in EU         Aeroplane       Ship         Road vehicle       Other         Identification       I.17.         Documentation references       I.17.         I.18. Description of commodity       I.19. Commodity code (HS code)         I.20. Quantity       I.20. Quantity         I.21. Temperature of product       I.22. Number of packages         Ambient       Chilled       Frozen         I.23. Seal/Container No       I.24. Type of packaging         I.25. Commodities certified for:       Technical use			
I.15. Means of transport       I.16. Entry BIP in EU         Aeroplane       Ship         Road vehicle       Other         Identification       I.17.         Documentation references       I.17.         I.18. Description of commodity       I.19. Commodity code (HS code)         I.20. Quantity       I.20. Quantity         I.21. Temperature of product       I.22. Number of packages         Ambient       Chilled       Frozen         I.23. Seal/Container No       I.24. Type of packaging         I.25. Commodities certified for:       Technical use	114. Date of departure		
Aeroplane       Ship       Railway wagon         Road vehicle       Other       I.17.         Identification       Documentation references       I.17.         I.18. Description of commodity       I.19. Commodity code (HS code)         I.11.       I.20. Quantity         I.21. Temperature of product       I.22. Number of packages         Ambient       Chilled       Frozen         I.23. Seal/Container No       I.24. Type of packaging         I.25. Commodities certified for:       Technical use			
Road vehicle       Other       I.17.         Identification       Documentation references       I.17.         I.18. Description of commodity       I.19. Commodity code (HS code)         I.20. Quantity       I.20. Quantity         I.21. Temperature of product       I.22. Number of packages         Ambient       Chilled       Frozen         I.23. Seal/Container No       I.24. Type of packaging         I.25. Commodities certified for:       Technical use	I.16. Entry BIP in EU		
Identification       Infraction         Documentation references       I.19. Commodity code (HS code)         I.18. Description of commodity       I.19. Commodity code (HS code)         I.20. Quantity       I.20. Quantity         I.21. Temperature of product       I.22. Number of packages         Ambient []       Chilled []       Frozen []         I.23. Seal/Container No       I.24. Type of packaging         I.25. Commodities certified for:       Technical use []			
I.18. Description of commodity       I.19. Commodity code (HS code)         I.20. Quantity         I.21. Temperature of product         Ambient □       Chilled □         Frozen □         I.23. Seal/Container No         I.25. Commodities certified for:         Technical use □			
I.21. Temperature of product       I.20. Quantity         I.21. Temperature of product       I.22. Number of packages         Ambient       Chilled         I.23. Seal/Container No       I.24. Type of packaging         I.25. Commodities certified for:       Technical use			
1.21. Temperature of product       I.22. Number of packages         Ambient       Chilled       Frozen         I.23. Seal/Container No       I.24. Type of packaging         I.25. Commodities certified for:       Technical use			
1.21. Temperature of product       I.22. Number of packages         Ambient       Chilled       Frozen         I.23. Seal/Container No       I.24. Type of packaging         I.25. Commodities certified for:       Technical use			
Ambient     Chilled     Frozen       1.23. Seal/Container No     I.24. Type of packaging       1.25. Commodities certified for:     Technical use			
1.23. Seal/Container No     1.24. Type of packaging       1.25. Commodities certified for:     Technical use			
I.25. Commodities certified for: Technical use			
Technical use			
1.26. For transit through EU to third country	I.27. For import or admission into EU		
Third country ISO code			
I.28. Identification of the commodities			
Species Nature of commodity Approval number of establishments Net weig (Scientific name) Manufacturing plant	ht		

COUNTRY			Apiculture by-products intended	exclusively for use in apiculture					
	п.	Health information	II.a. Certificate reference No	II.b.					
		I, the undersigned official veterinarian, declare that I have read and of the Council $(^{\rm 1a})$ and in particular Article 10 thereof, and (Chapter II thereof, and certify that the apiculture by-products of	Commission Regulation (EU) No 142/20	59/2009 of the European Parliament 11 ( <sup>1b</sup> ), and in particular Annex XIV,					
	II.1.	bject to any restrictions associated							
_									
(b) Acariosis ( <i>Acarapis woodi</i> (Rennie)); (c) Small hive beetle ( <i>Aethina tumida</i> ); and (d) Tropilaelaps mites ( <i>Tropilaelaps</i> spp.);									
Itific	(c) Small hive beetle ( <i>Aethina tumida</i> ); and								
° ≓		(d) Tropilaelaps mites (Tropilaelaps spp.);							
Part	11.2.	have been							
-		(2) either [subjected to a temperature of - 12 °C or lower for	or at least 24 hours.]						
		( <sup>2</sup> ) or [in the case of wax refined or processed in accor Annex IV to Regulation (EU) No 142/2011]	rdance with processing method 1-2-3-4	-5-7 ( <sup>2</sup> ) as set out in Chapter III of					
	Notes								
	Part I:								
		reference I.6: Person responsible for the consignment in the E amodity; it may be filled in if the certificate is for import commo		n only if it is a certificate for transit					
<ul> <li>Box reference I.11 and I.12: Approval number: the registration number of the establishment or plant, which has been issued by to authority.</li> </ul>									
	<ul> <li>Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit be stored in free zones, free warehouses and custom warehouses.</li> </ul>								
<ul> <li>Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); informa provided in the event of unloading and reloading.</li> </ul>			or name (ship); information is to be						
- Box reference I.19: use the appropriate HS code: 05.11.99 and specify the commodity as listed under note Box reference I.28			te Box reference I.28.						
	- Box	reference I.23: for bulk containers, the container number and t	the seal number (if applicable) should b	be given.					
	- Box	reference I.25: technical use: any use other than for animal co	onsumption.						
	- Box	reference I.26 and I.27: fill in according to whether it is a trans	sit or an import certificate.						
	- Box	reference I.28: Nature of commodity: means honey, beeswax,	royal jelly, propolis or pollen used in b	ee-keeping;					
	Part II:	1							
	( <sup>1a</sup> ) O	J L 300, 14.11.2009, p. 1.							
	( <sup>1b</sup> ) O	J L 54, 26.2.2011, p. 1.							
	( <sup>2</sup> ) Delete as appropriate.								
	— The	signature and the stamp must be in a different colour to that o	of the printing.						
	— Note for the person responsible for the consignment in the European Union: This certificate is only for veterinary purposes and h accompany the consignment until it reaches the border inspection post.								
Official veterinarian/Official inspector									
	Na	me (in capital letters):	Qualification and	title:					
	Dat	te:	Signature:						
	Sta	amp:							

# [<sup>F1</sup>CHAPTER 14(A)

# Health certificate

For fat derivatives not intended for human consumption to be used outside the feed chain, intended for dispatch to or for transit through  $(^2)$  the European Union]

COUNTRY Veterinary certificate to					
	1.1.	Consignor Name Address	I.2. Certificate reference No     I.2.a.     I.3. Central competent authority		
		Tel.	I.4. Local competent authority		
lent	1.5.	Consignee	I.6. Person responsible for the load in EU		
gnm		Name Address	Name Address		
onsi					
o pe		Postcode Tel.	Postcode Tel.		
tche					
Part I: Details of dispatched consignment	1.7.	Country of origin ISO code I.8. Region of origin Code	I.9. Country of ISO code I.10. Region of Code destination		
ails	I.11.	Place of origin	I.12. Place of destination		
t I: Deta		Name Approval number Address	Name Custom warehouse Address Approval number		
Par		Name Approval number Address	Postcode		
		Name Approval number Address			
	I.13.	Place of loading	I.14. Date of departure		
	l.15.	Means of transport	I.16. Entry BIP in EU		
	Aeroplane Ship Railway wagon				
		Road vehicle Other			
		Identification	1.17.		
		Documentation references			
	l.18.	Description of commodity	I.19. Commodity code (HS code)		
			I.20. Quantity		
	I.21.	Temperature of product	I.22. Number of packages		
		Ambient Chilled	Frozen		
	1.23.	Seal/Container No	I.24. Type of packaging		
	1.25.	Commodities certified for:			
		Technical use			
	I.26.	For transit through EU to third country	I.27. For import or admission into EU		
		Third country ISO code			
	1.28.	Identification of the commodities			
		Species Approval number of establishments (Scientific name) Manufacturing plant	Number of packages Net weight Batch number		

OUNTRY		Fat derivatives not intended for human consumption to be used outside the feed chain						
11.	Health info							
	and of the	and official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 of the European Parliament ouncil ( <sup>1a</sup> ) and in particular Article 10 thereof, and Commission Regulation (EU) No 142/2011 ( <sup>1b</sup> ), and in particular Chapter II thereto, and certify that the fat derivatives described above:						
5 II.1.	consist of fat derivatives that satisfy the health requirements below;							
II.2.	consist of fa	derivatives intended for purposes outside the feed chain, other than in cosmetics, pharmaceuticals and medical devices;						
II.1. II.2. II.3.		epared and stored in a plant approved, validated and supervised by the competent authority in accordance with Article 24 of C) No 1069/2009, in order to kill pathogenic agents;						
<b>Ч</b> а II.4.	have been	epared from rendered fats exclusively produced from the following materials:						
II.4.1.		at derivatives are intended for uses outside the feed chain, other than in organic fertilisers, soil improvers, cosmetics, als and medical devices, the following Category 1 materials:						
	(²) either	[- the following material:						
		(i) specified risk material;						
		(ii) entire bodies or parts of dead animals containing specified risk material at the time of disposal;]						
	(²) and/or	[- animal by-products which have been derived from animals which have been submitted to illegal treatment as defined in Article 1(2)(d) of Directive 96/22/EC or Article 2(b) of Directive 96/23/EC;]						
	(²) and/or							
II.4.2.	. in case the fat derivatives are intended for use in organic fertilisers or soil improvers or other uses outside the feed chain, other than cosmetics, pharmaceuticals and medical devices, the following Category 2 materials:							
	(²) either	<ul> <li>animal by-products containing residues of authorised substances or contaminants exceeding the permitted levels referred to in Article 15(3) of Directive 96/23/EC;]</li> </ul>						
	(²) and/or	[- products of animal origin which have been declared unfit for human consumption due to the presence of foreign bodies in those products;]						
( <sup>2</sup> ) and/or [- animals and parts of animals, other than those referred to in Articles 8 and 10 of Regulation (EC) No 1069 other than being slaughtered or killed for human consumption, including animals killed for disease co								
II.4.3.	the following Category 3 materials:							
	(²) either	[- carcases and parts of animals slaughtered or, in the case of game, bodies or parts of animals killed, and which are fit for human consumption in accordance with Union legislation, but are not intended for human consumption for commercial reasons:]						
	(²) and/or	[- carcases and the following parts originating either from animals that have been slaughtered in a slaughterhouse and were considered fit for slaughter for human consumption following an ante-mortem inspection or bodies and the following parts of animals from game killed for human consumption in accordance with Union legislation:						
	<ul> <li>carcases or bodies and parts of animals which are rejected as unfit for human consumption in accordance with U legislation, but which did not show any signs of disease communicable to humans;</li> </ul>							
		(ii) heads of poultry;						
		<ul> <li>(iii) hides and skins, including trimmings and splitting thereof, horns and feet, including the phalanges and the carpus and metacarpus bones, tarsus and metatarsus bones;</li> </ul>						
		(iv) pig bristles;						
		(v) feathers;]						
	(²) and/or	[- blood of animals which did not show any signs of disease communicable through blood to humans or animals, obtained from animals that have been slaughtered in a slaughterhouse after having been considered fit for slaughter for human consumption following an ante-mortem inspection in accordance with Union legislation;]						
	(²) and/or	[- animal by-products arising from the production of products intended for human consumption, including degreased bone, greaves and centrifuge or separator sludge from milk processing;]						

COUNTRY				Fat derivatives not intended for outside the feed chain	human consumption to be used		
Ш.	Health information				II.a. Certificate reference No	II.b.	
	( <sup>2</sup> ) and/or [- products of animal origin, or foodstuffs conta consumption for commercial reasons or due which no risk to public or animal health arise				to problems of manufacturing or packa		
	( <sup>2</sup> ) and/or [- petfood and feedingstuffs of animal origin, or no longer intended for feeding for commerci other defects from which no risk to public or				al reasons or due to problems of man		
	(²) and/or	[-		nta, wool, feathers, hair, horns, ho se communicable through that pr	oof cuts and raw milk originating from l roduct to humans or animals;]	ive animals that did not show signs	
	(²) and/or	[-		nals, and parts of such animals le to humans or animals;]	s, except sea mammals, which did	not show any signs of diseases	
	(²) and/or	[-	animal by-pro		inating from plants or establishments	manufacturing products for human	
	(²) and/or	[-		material originating from animal umans or animals:	Is which did not show any signs of d	lisease communicable through that	
			(i) shells fro	om shellfish with soft tissue or fle	ash;		
			(ii) the follow	ving originating from terrestrial a	nimals:		
			- hatch	ery by-products,			
			— eggs,				
			— egg b	py-products, including egg shells;			
			(iii) day-old (	chicks killed for commercial reas	ons;]		
II.5.	in case of fa	at de	rivatives produ	iced from animal by-products ref	erred to in point II.4.1 and point II.4.2:		
	(a) have been produced using the following methods:		the following methods:				
	(²) either	r	[transesterific acids and es		C, under corresponding appropriate pre	ssure, for 20 minutes (glycerol, fatty	
	(²) or		[saponificatio	n with NaOH 12M (glycerol and	soap):		
			(²) either	[in a batch process at 95 °C fo	for three hours;]		
			(²) or	[in a continuous process at 14	0 °C, 2 bars (2000 hPa) for eight minu	utes;]]	
	(²) or		[hydrogenatio	on at 160 °C at 12 bars (12000 h	Pa) pressure for 20 minutes;]		
				iners or in containers that have "NOT FOR HUMAN OR ANIM/	been cleaned, and all precautions are AL CONSUMPTION";	taken to prevent its contamination	
II.6.					red to in point II.4.3, the fat derivatives referred to in Chapter III of Annex IV		
Notes							
Part I:							
				le for the consignment in the Eu certificate is for import commodi	ropean Union: this box is to be filled i ty.	n only if it is a certificate for transit	
				tion: this box is to be filled in only buses and custom warehouses.	/ if it is a certificate for transit commod	ity. The products in transit can only	
				nber (railway wagons or containe e consignor must inform the BIP	er and lorries), flight number (aircraft) o of entry into the EU.	or name (ship) is to be provided. In	
— Box	I.19: use the	app	ropriate Harmo	onized System (HS) code under	the following headings: 15.16 or 15.08	3.	

#### Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011. (See end of Document for details)

### Fat derivatives not intended for human consumption to be used

COUNTRY	Fat derivatives not intended for human consumption to be used outside the feed chain			
II. Health information	II.a. Certificate reference No	II.b.		
- Box reference I.23: for bulk containers, the container number and the	e seal number (if applicable) should b	be included.		
- Box reference I.25: technical use: any use other than for animal cons	sumption.			
- Box reference I.26 and I.27: fill in according to whether it is a transit	or an import certificate.			
- Box reference I.28:				
Species: select from the following: Ruminantia, Other;				
Manufacturing plant: provide the registration number of treatment/prov	cessing establishment.			
Part II:				
( <sup>1a</sup> ) OJ L 300, 14.11.2009, p. 1.				
( <sup>1b</sup> ) OJ L 54, 26.2.2011, p. 1.				
( <sup>2</sup> ) Delete as appropriate.				
- The signature and the stamp must be in a different colour to that of	the printing.			
<ul> <li>Note for the person responsible for the consignment in the European U the consignment until it reaches the border inspection post.</li> </ul>	Inion: this certificate is only for veterina	ary purposes and has to accompany		
Official veterinarian/Official inspector				
Name (in capital letters):	Qualifica	ation and title:		
Date: Signature:				
Stamp:				

## CHAPTER 14(B)

### Health certificate

For fat derivatives not intended for human consumption to be used as feed or outside the feed chain, intended for dispatch to or for transit through (<sup>2</sup>) the European Union

cou	NTR	1	Veterinary certificate to EU		
	l.1.	Consignor	I.2. Certificate reference No I.2.a.		
		Name Address	I.3. Central competent authority		
		Address	I.4. Local competent authority		
1		Tel.			
men	1.5.	Consignee	I.6. Person responsible for the load in EU		
sign		Name Address	Name Address		
co					
ched		Postcode Tel.	Postcode Tel.		
of dispatched consignment	1.7.	Country of origin ISO code I.8. Region of origin Code	I.9. Country of ISO code I.10. Region of Code		
ofdi			destination destination		
tails		Diana of arisin			
Part I : Details	1.11.	Place of origin	I.12. Place of destination		
arl		Name Approval number Address	Name Custom warehouse Address Approval number		
e.		Name Approval number Address			
		Name Approval number Address	Postcode		
	I.13.	Place of loading	I.14. Date of departure		
<u> </u>	I.15.	Means of transport	I.16. Entry BIP in EU		
		Aeroplane Ship Railway wagon			
		Road vehicle Other	1.17.		
		Identification Documentation references			
	I.18.	Description of commodity	I.19. Commodity code (HS code)		
			15.16.10		
			I.20. Quantity		
	I.21.	Temperature of product	I.22. Number of packages		
			Frozen		
	1.23.	Seal/Container No	I.24. Type of packaging		
	1.25.	Commodities certified for:			
		Animal feedingstuff			
	1.26.	For transit through EU to third country	I.27. For import or admission into EU		
		Third country ISO code			
	1.28.	Identification of the commodities			
		Species Nature of commodity Approval number of (Scientific name) Manufacturi	, e		

cou	NTRY			Fat derivatives not intended for hur feed or outside the feed chain	man consumption to be used as			
	Ш.	Health info	ormation	II.a. Certificate reference No	II.b.			
	I, the undersigned official veterinarian, declare that I have Parliament and of the Council ( <sup>1a</sup> ) and in particular Article particular Annex XIV, Chapter II thereof, and certify that the			10 thereof, and Commission Regulation				
	II.1.	consist of fat derivatives that satisfy the health requirements below;						
ication	<ul> <li>II.2. consist of fat derivatives not intended for human consumption;</li> <li>II.3. have been prepared and stored in a plant approved, validated and supervised by the competent authority in accordance with Article of Regulation (EC) No 1069/2009, in order to kill pathogenic agents;</li> <li>II.4. have been prepared from rendered fats exclusively produced from the following Category 3 materials:</li> </ul>							
ll: Certif								
Part	11.4.	have been	prepared from rendered fats exclusively produced	from the following Category 3 materia	ls:			
		( <sup>2</sup> ) either	[- carcases and parts of animals slaughtered or, in human consumption in accordance with Union I reasons;]					
		(²) and/or	[- carcases and the following parts originating eithe considered fit for slaughter for human consumpti of animals from game killed for human consump	on following an ante-mortem inspection	or bodies and the following parts			
<ul> <li>(i) carcases or bodies and parts of animals which are rejected as unfit for human consumption in accordance will legislation, but which did not show any signs of disease communicable to humans or animals;</li> </ul>								
(ii) heads of poultry;								
	<ul> <li>(iii) hides and skins, including trimmings and splitting thereof, horns and feet, including the phalanges and the carpus ar metacarpus bones, tarsus and metatarsus bones, of animals, other than ruminants;</li> </ul>							
	(iv) pig bristles;							
	(v) feathers:]							
		(²) and/or	[- blood of animals which did not show any signs from animals other than ruminants that have be slaughter for human consumption following an a	en slaughtered in a slaughterhouse aft	ter having been considered fit for			
		(²) and/or	[- animal by-products arising from the production of greaves and centrifuge or separator sludge from		nption, including degreased bone,			
		(²) and/or	[- products of animal origin, or foodstuffs contain consumption for commercial reasons or due to which no risk to public or animal health arise;]					
	( <sup>2</sup> ) and/or [- petfood and feedingstuffs of animal origin, or feedingstuffs containing animal by-products or derived products, we no longer intended for feeding for commercial reasons or due to problems of manufacturing or packaging defects defects from which no risk to public or animal health arises;]							
	( <sup>2</sup> ) and/or [- blood, placenta, wool, feathers, hair, horns, hoof cuts and raw milk originating from live animals that did not show signs any disease communicable through that product to humans or animals;]							
		(²) and/or	[- aquatic animals, and parts of such animals, exc nicable to humans or animals;]	cept sea mammals, which did not sho	w any signs of diseases commu-			
		(²) and/or	[- animal by-products from aquatic animals origin consumption;]	ating from plants or establishments m	anufacturing products for human			
		(²) and/or	[- the following material originating from animals material to humans or animals:	which did not show any signs of dis	ease communicable through that			
			(i) shells from shellfish with soft tissue or flesh;					

COUNTR	ΥY	Fat derivatives not intended for hu feed or outside the feed chain	man consumption to be used as		
Ш.	Health information	II.a. Certificate reference No	II.b.		
	(ii) the following originating from terrestrial a	animals:			
	- hatchery by-products,				
	— eggs,				
	- egg by-products, including egg shells	ç.			
	(iii) day-old chicks killed for commercial reas	sons;]			
II.5.	are packaged in new containers or in containers which l cleaned, and all precautions are taken to prevent its con		CONSUMPTION', that have been		
Notes					
Part I:					
	reference I.6: Person responsible for the consignment in the modity; it may be filled in if the certificate is for import com		n only if it is a certificate for transit		
— Box auth	reference I.11 and I.12: Approval number: the registration nurrity.	mber of the establishment or plant, which	has been issued by the competent		
	reference I.12: Place of destination: this box is to be filled in tored in free zones, free warehouses and custom warehous		ty. The products in transit can only		
	reference I.15: Registration number (railway wagons or con ided in case of unloading and reloading.	ainer and lorries), flight number (aircraft) o	r name (ship); information is to be		
— Box	- Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be included.				
— Box	- Box reference I.25: technical use: any use other than for animal consumption.				
— Box	reference I.26 and I.27: fill in according to whether it is a tr	ansit or an import certificate.			
— Box	reference I.28: Manufacturing plant: provide the registration	number of treatment/processing establishr	nent.		
Part II:					
( <sup>1a</sup> ) OJ	L 300, 14.11.2009, p. 1.				
( <sup>1b</sup> ) OJ	L 54, 26.2.2011, p. 1.				
(²) De	lete as appropriate.				
— The	signature and the stamp must be in a different colour to the	at of the printing.			
— Note acco	for the person responsible for the consignment in the E mpany the consignment until it reaches the border inspection	uropean Union: this certificate is only for on post.	r veterinary purposes and has to		
Official	veterinarian/Official inspector				
Name	e (in capital letters):	Qualification ar	nd title:		
Date:		Signature:			
Stam	p:				

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011. (See end of Document for details)

# [<sup>F1</sup>CHAPTER 15

## Health certificate

For egg products not intended for human consumption that could be used as feed material, intended for dispatch to or for transit through (<sup>2</sup>) the European Union]

-00	NIR	1	veterinary certificate to EU			
	l.1.	Consignor Name	I.2. Certificate reference No I.2.a.			
		Address	I.3. Central competent authority			
		Tel.	I.4. Local competent authority			
ent	I.5.	Consignee	I.6. Person responsible for the load in EU			
gnm		Name Address	Name Address			
onsi						
ğ		Postcode Tel.	Postcode Tel.			
tche	1.7					
ispa	1.7.	Country of origin ISO code I.8. Region of origin Code	I.9. Country of ISO code I.10. Region of Code destination			
of d						
Part I: Details of dispatched consignment	l.11.	Place of origin	I.12. Place of destination			
Det		Name Approval number	Name Custom warehouse			
Ë		Address	Address Approval number			
Ра		Name Approval number Address	Postcode			
		Name Approval number				
		Address				
	l.13.	Place of loading	I.14. Date of departure			
_	115	Means of transport	I.16. Entry BIP in EU			
	1.10.					
		Aeroplane Ship Railway wagon Road vehicle Other				
			1.17.			
		Documentation references				
	I.18.	Description of commodity	I.19. Commodity code (HS code)			
			I.20. Quantity			
	I.21.	Temperature of product	I.22. Number of packages			
		Ambient Chilled	Frozen			
	1.23.	Seal/Container No	I.24. Type of packaging			
	I.25.	Commodities certified for:	ŀ			
		Animal feedingstuff  Technica	use			
	I.26.	For transit through EU to third country	I.27. For import or admission into EU			
		Third country ISO code				
	1.28.	Identification of the commodities				
		Approval number of establishments Number of Manufacturing plant	ackages Net weight Batch number			

соц	INTRY		Egg products not intended for human consumption that cou used as feed	uld be					
	П.	Health infor	rmation II.a. Certificate reference No II.b.						
		I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 of the European Parliament and of the Council ( <sup>1a</sup> ) and in particular Article 10 thereof, and Commission Regulation (EU) No 142/2011 ( <sup>1b</sup> ), and in particular Chapter I of Annex XIV thereto, and certify that the egg products described above:							
ion	11.1.	consist of egg products that satisfy the health requirements below;							
ificat	11.2.	consist exclusively of egg products not intended for human consumption;							
Part II: Certification	II.3.	have been prepared and stored in a plant, approved, validated and supervised by the competent authority in accordance with Article 24 of Regulation (EC) No 1069/2009 or Article 4(2) of Regulation (EC) No 853/2004 of the European Parliament and of the Council ( <sup>3</sup> ), in order to kill pathogenic agents;							
	11.4.	have been prepared (derived) exclusively with the following animal by-products:							
		(²) either	[- animal by-products arising from the production of products intended for human consumption:]						
		(²) and/or	[- products of animal origin, or foodstuffs containing products of animal origin, which are no longer intended for h consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects which no risk to public or animal health arise;]						
		(²) and/or	[- the following material originating from terrestrial animals which did not show any signs of disease communicable th that material to humans or animals:	rough					
			- hatchery by-products,						
			— eggs,						
			— egg by-products, including egg shells;]						
	II.5.	have been subjected to processing:							
		(²) either	[in accordance with processing method	i (EU)					
		(²) or	[in accordance to a method and parameters which ensure that the products comply with the microbiological standard out in Chapter I of Annex X, to Regulation (EU) No 142/2011;]	ls set					
		(²) or	[in accordance with Section X, Chapters I and II of Annex III to Regulation (EC) No 853/2004;]						
	II.6.	have been e following star	examined by the competent authority taking a random sample immediately prior to dispatch and found it to comply wit andards ( <sup>5</sup> ):	th the					
		Salmonella:	absence in 25g: $n = 5$ , $c = 0$ , $m = 0$ , $M = 0$ ,						
		Enterobacteri	riaceae: n = 5, c = 2, m = 10, M = 300 in 1 gram;						
	II.7.		standards on residues of substances that are harmful or might alter the organoleptic characteristics of the product or ma I dangerous or harmful to animal health;	ke its					
	II.8.	the end prod	duct was:						
		(²) either	[packed in new or sterilised bags,]						
		(²) or	[transported in bulk in containers or other means of transport that were thoroughly cleaned and disinfected with a disinfe approved by the competent authority before use,]	ectant					
		and which be	pear labels indicating "NOT FOR HUMAN CONSUMPTION";						
	11.9.	the end prod	duct was stored in enclosed storage;						
	II.10.	the product h	has undergone all precautions to avoid contamination with pathogenic agents after treatment.						
	Notes	-							
	Part I:								
	— Box		S: Person responsible for the consignment in the European Union: this box is to be filled in only if it is a certificate for tay be filled in if the certificate is for import commodity.	ransit					

II. Health information	II.a. Certificate reference No	II.b.		
<ul> <li>Box reference I.12: Place of destination: this box is to be filled in only be stored in free zones, free warehouses and custom warehouses.</li> </ul>	— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.			
	<ul> <li>Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship) is to be provided. case of unloading and reloading, the consignor must inform the BIP of entry into the EU.</li> </ul>			
- Box I.19: use the appropriate Harmonized System (HS) code under	the following headings: 04.08, 23.09 c	r 35.02.		
- Box reference I.23: for bulk containers, the container number and the	e seal number (if applicable) should b	e included.		
- Box reference I.25: technical use: any use other than for animal cor	nsumption.			
- Box reference I.26 and I.27: fill in according to whether it is a transi	t or an import certificate.			
Part II:				
( <sup>1a</sup> ) OJ L 300, 14.11.2009, p. 1.				
( <sup>1b</sup> ) OJ L 54, 26.2.2011, p. 1.				
( <sup>2</sup> ) Delete as appropriate.				
( <sup>3</sup> ) OJ L 139, 30.4.2004, p. 55.				
( <sup>4</sup> ) Insert method 1 to 5 or 7 as applicable.				
( <sup>5</sup> ) Where:				
n = number of samples to be tested;				
<ul> <li>m = threshold value for the number of bacteria; the result is consid m;</li> </ul>	lered satisfactory if the number of bacte	eria in all samples does not exceed		
M = maximum value for the number of bacteria; the result is considered or more; and	lered unsatisfactory if the number of ba	cteria in one or more samples is M		
c = number of samples the bacterial count of which may be betwee count of the other samples is m or less.	een m and M, the sample still being co	nsidered acceptable if the bacterial		
- The signature and the stamp must be in a different colour to that of	the printing.			
<ul> <li>Note for the person responsible for the consignment in the European the consignment until it reaches the border inspection post.</li> </ul>	Union: this certificate is only for veterina	ry purposes and has to accompany		
Official veterinarian/Official inspector				
Name (in capital letters):	Qualificat	tion and title:		
Date:	Signature	a:		
Stamp:				

### CHAPTER 16

#### **Model declaration**

Declaration by the importer of bones and bone products (excluding bone meal), horns and horn products (excluding horn meal) and hooves and hoof products (excluding hoof meal) intended for use other than as feed material, organic fertilisers or soil improvers for dispatch to the European Union

Note for the importer: This declaration is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

I, the undersigned, declare that the following products (1):

(a) bones and bone products (excluding bone meal);

(b) horns and horn products (excluding horn meal);

(c) hooves and hoof products (excluding hoof meal);

are intended to be imported by me into the Union, and I declare that these products will not be diverted at any stage for any use in food, feed material, organic fertilisers or soil improvers and will be conveyed directly for the purpose of further processing or treatment to:

Name:		Address:	
-------	--	----------	--

Furthermore, I declare that the product does not contain and is not derived from specified risk material as defined in Annex V to Regulation (EC) No 999/2001 or mechanically separated meat obtained from bones of bovine, ovine or caprine animals.

The importer:

Name:		Address:	
-------	--	----------	--

Done at ..... on ..... (place)

(date)

Signature .....

.....

Reference number as indicated on the Common Veterinary Entry Document (CVED) provided for in Annex III to Commission Regulation (EC) No 136/2004:

Official stamp of the border inspection post of entry into the EU (2)

Signature: .....

(Signature of the official veterinarian of the border inspection post) (2)

Name: .....

(Name in capital letters)

<sup>(1)</sup> Delete as appropriate.

<sup>(2)</sup> The signature and the stamp must be in a different colour to that of the printing.

Status: Point in time view as at 23/02/2015.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011. (See end of Document for details)

### CHAPTER 17

### Health certificate

For processed manure, derived products from processed manure and guano from bats intended for dispatch to or for transit through  $\binom{2}{1}$  the European Union

COUNTRY			Veterinary certificate to EU
	l.1.	Consignor	I.2. Certificate reference No I.2.a.
		Name	I.3. Central competent authority
		Address	
		Tel.	I.4. Local competent authority
	1.5.	Consignee	I.6. Person responsible for the load in EU
men		Name	Name
ign		Address	Address
suo			
o p		Postcode	Postcode
tche		Tel.	Tel.
dispatched consignment	1.7.	Country of origin ISO code I.8. Region of origin Code	I.9. Country of ISO I.10. Region of Code
of di			destination code destination
ls o			
Part I: Details	1.11.	Place of origin	I.12. Place of destination
		Name Approval number	Name Custom warehouse
Part		Address	Address Approval number
-		Name Approval number Address	
		Name Approval number	Postcode
		Address	
	I.13.	Place of loading	I.14. Date of departure
		-	
	l.15.	Means of transport	I.16. Entry BIP in EU
		Aeroplane Ship Railway wagon	
		Road vehicle Other	1.17.
		Identification	1.17.
		Documentation references	
	I.18.	Description of commodity	I.19. Commodity code (HS code)
			I.20. Quantity
			I.20. sevenny
	I.21.	Temperature of product	I.22. Number of packages
		Ambient Chilled	Frozen
	1.23.	Seal/Container No	I.24. Type of packaging
	1.25.	Commodities certified for:	1
		_	
	1.26.	For transit through EU to third country	I.27. For import or admission into EU
		Third country ISO code	
	1.28.	Identification of the commodities	
		Species Nature of commodity	Approval number of establishments Net weight
		(Scientific name)	Manufacturing plant

co	UNTRY		Processed manure, derived produc guano from bats	cts from processed manure and				
	П.	Health information	II.a. Certificate reference No	II.b.				
I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 of the Europea and of the Council ( <sup>1a</sup> ) and in particular Article 9 thereof, and Commission Regulation (EU) No 142/2011 ( <sup>1b</sup> ), and in particula Chapter II thereof, and certify that the processed manure, the derived products from processed manure and the guano from ba above:								
tion	II.1.	come from a plant for the manufacture of products for purposes other than feeding to farmed animals, a biogas plant or a composting plant approved by the competent authority of the third country meeting the special conditions laid down in Regulation (EC) No 1069/2009 and in Regulation (EU) No 142/2011;						
tifica	II.2.( <sup>2</sup> )	have been subjected to:	have been subjected to:					
II: Certification		[a heat treatment process of at least 70 °C for at least 60 minutes;] or						
Part I		[an equivalent treatment validated and authorised by the importing Member State in accordance with the specific conditions laid down in Regulation (EC) No 1069/2009 and in Regulation (EU) No 142/2011 as follows:						
				;				
	11.3.	are:						
		(a) free from Salmonella (no salmonella in 25 g treated product);						
	(b) free from Escherichia coli or from Enterobacteriaceae (based on the aerobic count: less than 1 000 cfu per gram of treated proc and							
		have been subjected to reduction in spore-forming bacteria and	l toxin formation;					
	11.4.	are securely enclosed in:						
		(a) well-sealed and insulated containers; or						
		(b) properly sealed packs (plastic bags or 'big bags').						
	Notes							
	Part I:							
		reference I.6: Person responsible for the consignment in the Eur modity; it may be filled in if the certificate is for import commodit		n only if it is a certificate for transit				
		reference I.11 and I.12: Approval number: the registration numbe ority.	er of the establishment or plant, which	has been issued by the competent				
		reference I.12: Place of destination: this box is to be filled in only tored in free zones, free warehouses and custom warehouses.	r if it is a certificate for transit commodi	ty. The products in transit can only				
		reference 1.15: Registration number (railway wagons or containe ided in the event of unloading and reloading.	r and lorries), flight number (aircraft) o	r name (ship); information is to be				
	— Box	reference I.23: for bulk containers, the container number and the	e seal number (if applicable) should be	e given.				
	— Box	reference I.25: technical use: any use other than for animal con-	sumption.					
	— Box	reference I.26 and I.27: fill in according to whether it is a transit	t or an import certificate.					
	— Box	reference I.31: Nature of commodity: enter if processed manure	, derived products from processed ma	nure or guano from bats.				
	Part II:							
	( <sup>1a</sup> ) OJ	I L 300, 14.11.2009, p. 1.						
	( <sup>1b</sup> ) OJ	OJ L 54, 26.2.2011, p. 1.						

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011. (See end of Document for details)

COUNTRY	Processed manure, derived products from processed manure and guano from bats				
II. Health information	II.a. Certificate reference No	II.b.			
( <sup>2</sup> ) Delete as appropriate.					
- The signature and the stamp must be in a different colour to that of the printing.					
<ul> <li>Note for the person responsible for the consignment in the European Union: This certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.</li> </ul>					
Official veterinarian/Official inspector					
Name (in capital letters):	Qualification and	l title:			
Date:	Signature:				
Stamp:					

## CHAPTER 18

### Health certificate

For horns and horn products, excluding horn meal, and hooves and hoof products, excluding hoof meal, intended for the production of organic fertilisers or soil improvers intended for dispatch to or for transit through  $(^{2})$  the European Union

cou	COUNTRY			Veterinary certificate to EU		
	l.1.	Consignor		I.2. Certificate reference No I.2.a.		
		Name		I.3. Central competent authority		
		Address		I.4. Local competent authority		
		Tel.				
ent	1.5.	Consignee	I.6. Person responsible for the load in EU			
gnm		Name Address		Name Address		
onsi		Address		Address		
pa		Postcode		Postcode		
dispatched consignment		Tel.		Tel.		
disp	1.7.	Country of origin ISO code I.8. Region of origin Co	de	I.9. Country of ISO code I.10. Region of Code destination		
ď						
Part I: Details	l.11.	Place of origin		I.12. Place of destination		
11 H		Name Approval number Address		Name Custom warehouse Address Approval number		
Pal		Name Approval number				
		Address		Postcode		
		Name Approval number Address				
	I.13.	Place of loading		I.14. Date of departure		
	l.15.	Means of transport		I.16. Entry BIP in EU		
		Aeroplane 🗌 Ship 🗋 Railway wagon 🗋				
		Road vehicle Other		I.17. Number(s) of CITES		
		Identification Documentation references				
	l.18.	Description of commodity		I.19. Commodity code (HS code)		
				I.20. Quantity		
	1.21.	Temperature of product		I.22. Number of packages		
		Ambient Chilled		Frozen		
	1.23.	Seal/Container No		I.24. Type of packaging		
	1.25.	Commodities certified for:				
		Further process  Technical use				
	1.26.	6. For transit through EU to third country		I.27. For import or admission into EU		
		Third country ISO code				
	1.28.	Identification of the commodities				
		Species Approval number of establishme (Scientific name) Manufacturing plant	ents	Net weight Batch number		

со	UNTRY			Horns and horn products, exclude hoof products, excluding hoof me organic fertilisers or soil improver	al, intended for the production of		
	П.	Health inf	ormation	II.a. Certificate reference No	II.b.		
		and of the	Council (1a), and Commission Regulation (EU) No 14	and understood Regulation (EC) No 1069/2009 of the European Parliament t2/2011 ( <sup>1b</sup> ), and in particular Annex XIV, Chapter II thereof, and certify that s and hoof products, excluding hoof meal ( <sup>2</sup> ) described above:			
on	II.1.	( <sup>2</sup> ) either	[originate from animals that were slaughtered in a s result of such inspection, for slaughter for human of		nterhouse, after undergoing ante-mortem inspection, and were fit, as a imption;]		
ertificati		( <sup>2</sup> ) or	[originate from animals that did not show clinical animals;]	signs of any disease communicable	through that product to humans or		
Part II: Certification	II.2.	II.2. horns, horn products, hooves and hoof products must have undergone a heat treatment for one hour at a core temperature of at least 80 °C;					
-	11.3.	horns mus	t have been removed without opening the cranial ca	vity;			
	II.4.	II.4. at any stage of processing, storage or transport every precaution shall be taken to avoid cross-contamination.					
	II.5.	the horns	and horn products, excluding horn meal, and hooves	s and hoof products, excluding hoof m	eal, were packed:		
	( <sup>2</sup> ) either [in new packaging or containers;]						
	( <sup>2</sup> ) or [in vehicles or bulk containers disinfected prior to loading using a product approved by the competent authority;]						
		and	[the packaging or containers are marked so as to in FOR HUMAN AND ANIMAL CONSUMPTION' and				
	II.6.						
		( <sup>2</sup> ) either	[the product does not contain and is not derived fr 999/2001 of the European Parliament and of the C ovine or caprine animals; and the animals from wi means of gas injected into the cranial cavity or killed by means of an elongated rod-shaped instrument i	ouncil ( <sup>4</sup> ) or mechanically separated m hich this product is derived have not I by the same method or slaughtered by	neat obtained from bones of bovine, been slaughtered after stunning by		
		( <sup>2</sup> ) or	[the product does not contain and is not derived fron born, continuously reared and slaughtered in a cou accordance with Article 5(2) of Regulation (EC) No	intry or region classified as posing a i			
	Notes						
	Part I:						
			.6: Person responsible for the consignment in the Eu hay be filled in if the certificate is for import commod		in only if it is a certificate for transit		
		reference I nority.	.11 and I.12: Approval number: the registration numb	er of the establishment or plant, which	has been issued by the competent		
			.12: Place of destination: this box is to be filled in only e zones, free warehouses and custom warehouses.	/ if it is a certificate for transit commod	ity. The products in transit must only		
	- Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in the event of unloading and reloading.						
	— Вох	reference I	.23: for bulk containers, the container number and th	ne seal number (if applicable) must be	given.		
	— Вох	reference I	.25: technical use: any use other than for animal cor	nsumption.			
	— Вох	reference I	.26 and I.27: fill in according to whether it is a trans	it or an import certificate.			
	— Box	reference I	.28: Nature of commodity.				

COUNTRY		Horns and horn products, exclud hoof products, excluding hoof mea organic fertilisers or soil improver	al, intended for the production of		
П.	Health information	II.a. Certificate reference No	II.b.		
Part	II:	·			
( <sup>1a</sup> ) (	OJ L 300, 14.11.2009, p. 1.				
( <sup>1b</sup> )	( <sup>1b</sup> ) OJ L 54, 26.2.2011, p. 1.				
(²)	( <sup>2</sup> ) Delete as appropriate.				
(3) .	Type of product: horns, horn products, hooves, hoof products.				
(4)	OJ L 147, 31.5.2001, p. 1.				
— т	he signature and the stamp must be in a different colour to that of	the printing.			
	<ul> <li>Note for the person responsible for the consignment in the European Union: this certificate is only for veterinary purposes and must accompany the consignment until it reaches the border inspection post.</li> </ul>				
Offic	ial veterinarian/Official inspector				
	Name (in capital letters):	Qualification and	title:		
	Date:	Signature:			
	Stamp:				

#### CHAPTER 19

## Health certificate

For gelatine not intended for human consumption to be used by the photographic industry, intended for dispatch to the European Union

cou	NTR	(						Veterinary certific	ate to EU
	l.1.	Consignor			I.2. Certificat	te reference No		I.2.a.	
		Name		ł					
	Address 1.3.		I.3. Central of	competent author	ority				
		Tel.			I.4. Local co	mpetent authori	ity		
ŧ	1.5.	Consignee			I.6. Person	responsible for	the load	in EU	
me		Name			Name				
sign		Address			Address				
dispatched consignment		Postcode Tel.			Postcod Tel.	e			
of dispa	I.7.	Country of origin ISO code	I.8. Region of origin	Code	I.9. Country destinati		) code	I.10. Region of destination	Code
ails									
Part I: Details of	1.11.	Place of origin			I.12. Place of	destination			
÷		Name	Approval number		Name			Custom warehouse	
Pai		Address	Approval hambol		Address			Approval number	
		Name	Approval number						
		Address	•		Postcod	e			
		Name Address	Approval number						
	l.13.	Place of loading			I.14. Date of	departure			
	l.15.	.15. Means of transport			I.16. Entry BI	P in EU			
		Aeroplane 🗌 Ship [	Railway wagon	o					
		Road vehicle D Other			I.17. Number	(s) of CITES			
		Identification							
		Documentation references							
	l.18.	Description of commodity				I.19. Commodity code (HS code) 35.03			
							1.20. Q	uantity	
	I.21.	Temperature of product	_		_		1.22. Nu	umber of packages	
		Ambient 🔲	Chilled	-	Frozen 🗌				
	1.23.	Seal/container No			I.24. Type of packaging				
	1.25.	Commodities certified for:					1		
		Technical use							
	1.26.				I.27. For impo	ort or admission	into EU		
	1.28.	Identification of the commoditie	s						
		Species (Scientific name)	Approval number of esta Manufacturing pl		ents	Net	weight	Batch n	umber

cou	NTRY		Gelatine not intended for human or photographic industry	consumption to be used by the			
	П.	Health information	II.a. Certificate reference No	II.b.			
		I, the undersigned official, declare that I have read and under the Council ( <sup>Ia</sup> ) and in particular Articles 8 and 10 thereof, an XIV, Chapter II thereof, and certify that the photographic gela	d Commission Regulation (EU) No 142				
	II.1. consists exclusively of photographic gelatine for photographic uses and is not intended for any other purpose;						
<ul> <li>II.2. has been prepared and stored in a plant registered and supervised by the competent authority in accordance with A Regulation (EC) No 1069/2009, which does not produce gelatine for food, feed or other uses intended for dispatch to the Union;</li> <li>II.3. has been prepared with Category 3 animal by-products and/or bovine vertebral column classified as Category 1 material;</li> <li>II.4. has been wrapped, packaged in new containers, stored and transported in sealed, leak-proof labelled containers in a vertebral column.</li> </ul>							
: Cer	11.3.	has been prepared with Category 3 animal by-products and/o	r bovine vertebral column classified as	Category 1 material;			
II.4. has been wrapped, packaged in new containers, stored and transported in sealed, leak-proof labelled containers in a vehic satisfactory hygiene conditions;							
	II.5. has been produced by a process ensuring that the raw material is:						
		( <sup>3</sup> ) either treated by pressure sterilisation as referred to in de	efinition No 19 of Article 3 of Regulation	on (EC) No 1069/2009 ( <sup>2</sup> );			
		( <sup>3</sup> ) or subjected to:					
	(i) treatment with acid for at least two days, washing with water and treatment with an alkaline solution for at least 20 days; the pH must be adjusted and the material purified by means of filtration and sterilised at 138-140 °C for 4 seconds; or						
(ii) treatment with alkali for at least two days, washing with water and treatment with an acid solution for 10-12 the pH must be adjusted and the material purified by means of filtration and sterilised at 138-140 °C for 4 so							
	II.6. has been wrapped and packaged in wrappings and packages carrying the words 'PHOTOGRAPHIC GELATINE FOR THE PHOTOGRAPHIC INDUSTRY ONLY'.						
	Notes						
	Part I:						
	— Box r Kingd	reference I.5: The intended destination of the photographic ge dom.	latine can only be the Czech Republ	ic, the Netherlands or the United			
	— Box r	reference I.9: Country of destination: only applicable for the Cze	ech Republic, the Netherlands or the U	Inited Kingdom.			
	- Box re autho	reference I.11 and I.12: Approval number: the registration numbe prity.	r of the establishment or plant, which I	has been issued by the competent			
		reference I.15: Registration number (railway wagons or contained ded in the event of unloading and reloading.	r and lorries), flight number (aircraft) o	r name (ship); information is to be			
	— Box n	reference I.23: Identification of container/seal number: only when	e applicable.				
	- Box reference I.25: technical use: any use other than for animal consumption.						
	Part II:						
	( <sup>1a</sup> ) OJ L 300, 14.11.2009, p. 1.						
	( <sup>1b</sup> ) OJ	L 54, 26.2.2011, p. 1.					
	( <sup>2</sup> ) Pres	ssure sterilisation (method 1) is also referred to in Chapter III o	f Annex IV to Regulation (EU) No 142	/2011 as follows:			
	'Rec	duction					
	<ol> <li>If the particle size of the animal by-products to be processed is more than 50 millimetres, the animal by-products must be reduced in size using appropriate equipment, set so that the particle size after reduction is no greater than 50 millimetres. The effectiveness of the equipment must be checked daily and its condition recorded. If checks disclose the existence of particles larger than 50 millimetres, the process must be stopped and repairs made before the process is resumed.</li> </ol>						

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011. (See end of Document for details)

cou	NTRY	Gelatine not intended for human ophotographic industry	consumption to be used by the			
П.	Health information	II.a. Certificate reference No	II.b.			
	Time, temperature and pressure					
	2. The animal by-products with the particle size of no greater than 50 millimetres must be heated to a core temperature of more than 133 °C for at least 20 minutes without interruption at a pressure (absolute) of at least 3 bars. The pressure must be produced by the evacuation of all air in the sterilisation chamber and the replacement of the air by steam ("saturated steam"); the heat treatment may be applied as the sole process or as a pre- or post-process sterilisation phase.					
	3. The processing may be carried out in batch or continuous systems.'					
( <sup>3</sup> )	Delete as appropriate.					
- ·	The signature and the stamp must be in a different colour to that of	the printing.				
	Note for the person responsible for the load in the European Union: consignment until it reaches the factory of destination from the borde		rposes and has to accompany the			
Offi	cial veterinarian/Official inspector					
Ν	lame (in capital letters):	Qualification an	d title:			
0	Date: Signature:					
s	Stamp:					

# [<sup>F3</sup>CHAPTER 20

### Model declaration

Declaration for the import from third countries and for the transit through the European Union of intermediate products to be used for the manufacture of medicinal products, veterinary medicinal products, medical devices for medical and veterinary

COUN	ITRY:					Vete	erinary certificat	te to EU
	l.1.	Consignor		Certificate referen	ice No	1.2.a	a	
		Name	1.3.	I.3. Central competent authority				
		Address	1.4.	Local competent a	authority			
		Tel.		Loodi competent	addionty			
ent	1.5.	Consignee Name		Person responsib Name	le for the loa	d in El	J	
nsignm		Address		Address				
ned cor		Postcode Tel.		Postcode Tel.				
Part I: Details of dispatched consignment	1.7.	Country of ISO code I.8. Region of Code origin	1.9.	Country of destination	ISO code	l.10.	Region of destination	Code
Details	l.11.	Place of origin		Place of destination	on			
÷		Name Approval number			Custom	wareh	ouse 🛛	
Pai		Address		Name Approval number			er	
		Name Approval number		Address				
		Address						
		Name Approval number		Postcode				
	I.13.	Address Place of loading	1.14.	Date of departure				
	1.13.	Flace of loading	1.14.					
	I.15.	Means of transport	I.16.	Entry BIP in EU				
		Aeroplane 🛛 Ship 🗖 Railway wagon 🗖						
			I.17.					
		Identification Documentation references						
	I.18.	Description of commodity		l.º	19. Comm	odity c	ode (HS code)	
						1.20.	Quantity	
	I.21.	Temperature of product	F	rozen 🗖		1.22.	Number of pac	kages
	1.23.	Seal/Container No				I.24.	Type of packag	ging
	1.25.	Commodities certified for:						
		Technical use						

## purposes, active implantable medical devices, in vitro diagnostics medical devices for medical and veterinary purposes, laboratory reagents and cosmetic products]

1.26.	For transit through EU to thir	d country	1.27.	For import or admission into EU	
	Third country	ISO code			
1.28.	Identification of the commodities				
	Approval number of establishments				
	Species (Scientific name)	Manufacturing plant		Net weight	Batch number

Part II: Certification

#### Status: Point in time view as at 23/02/2015. Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011. (See end of Document for details)

medicinal products, veterinary medicinal products, medical devices for medical and veterinary purposes, active implantable medical devices, in vitro diagnostics medical devices for medical and veterinary purposes, COUNTRY laboratory reagents, and cosmetic products Health information Certificate reference No Ш II.a. ll b DECLARATION I, the undersigned, declare that the intermediate product referred to above is intended to be imported by me into the Union and satisfies the definition provided for in point 35 of Annex I of Commission Regulation (EU) No 142/2011 (<sup>1a</sup>), and in particular that (1) it is intended for the manufacture of: (2) either medicinal products,] (2) and/or veterinary medicinal products.] (2) and/or medical devices for medical and veterinary purposes,] [— (2) and/or active implantable medical devices,] [---(2) and/or in vitro diagnostic medical devices for medical and veterinary purposes.] [-(<sup>2</sup>) and/or laboratory reagents.] [— (2) and/or cosmetic products;] [---(2) its design, transformation and manufacturing stages have been sufficiently completed in order to qualify the material directly or as a component of a product intended for that purpose, except for the fact that it requires further manufacturing or transformation such as mixing, coating, assembling or packaging to make it suitable for placing on the market or putting into service as medicinal products, veterinary medicinal products, medical devices for medical and veterinary purposes, active implantable medical devices, in vitro diagnostic medical devices for medical and veterinary purposes or cosmetic products in accordance with the Union legislation (1b) applicable to those products or as laboratory reagents; (3) it has been derived from: (2) either material which may have originated from animals submitted to illegal treatment as defined in [-Article 1(2)(d) of Council Directive 96/22/EC or Article 2(b) of Council Directive 96/23/EC;] carcases and parts of animals slaughtered or, in the case of game, bodies or parts of animals killed, and (<sup>2</sup>) and/or which are fit for human consumption in accordance with Union legislation, but are not intended for human consumption for commercial reasons;] (<sup>2</sup>) and/or carcases and the following parts originating either from animals that have been slaughtered in a slaughterhouse and were considered fit for slaughter for human consumption following an ante-mortem inspection or bodies and the following parts of animals from game killed for human consumption in accordance with Union legislation: carcases or bodies and parts of animals which are rejected as unfit for human consumption in (i) accordance with Union legislation, but which did not show any signs of disease communicable to humans or animals; heads of poultry: (ii) hides and skins, including trimmings and splitting thereof, horns and feet, including the phalanges (iii) and the carpus and metacarpus bones, tarsus and metatarsus bones, of animals other than ruminants; (iv) pig bristles; (v) feathers:1 (<sup>2</sup>) and/or blood of animals which did not show any signs of disease communicable through blood to humans or animals obtained from animals other than ruminants that have been slaughtered in a slaughterhouse after having been considered fit for slaughter for human consumption following an ante-mortem inspection in accordance with Union legislation;] animal by-products arising from the production of products intended for human consumption, including (2) and/or degreased bone, greaves and centrifuge or separator sludge from milk processing;]

Intermediate products to be used for the manufacture of

COUNTRY	r	Intermediate products to be used for the manufacture of medicinal products, veterinary medicinal products, medical devices for medical and veterinary purposes, active implantable medical devices, in vitro diagnostics medical devices for medical and veterinary purposes, laboratory reagents, and cosmetic products			
П.	Health infor				
(²) and/or	[—	products of animal origin, or foodstuffs containing products of animal origin, which are no longer intended for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arise;]			
(²) and/or	· [—	pet food and feedingstuffs of animal origin, or feedingstuffs containing animal by-products or derived products, which are no longer intended for feeding for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arises;]			
(²) and/or	· [—	blood, placenta, wool, feathers, hair, horns, hoof cuts and raw milk originating from live animals that did not show signs of any disease communicable through that product to humans or animals;]			
( <sup>2</sup> ) and/or	[—	aquatic animals, and parts of such animals, except sea mammals, which did not show any signs of diseases communicable to humans or animals;]			
(²) and/or	· [—	animal by-products from aquatic animals originating from plants or establishments manufacturing products for human consumption;]			
(²) and/or	· [—	the following material originating from animals which did not show any signs of disease communicable through that material to humans or animals:			
		(i) shells from shellfish with soft tissue or flesh;			
		(ii) the following originating from terrestrial animals:			
		— hatchery by-products,			
		— eggs,			
		<ul> <li>egg by-products, including egg shells;</li> </ul>			
		(iii) day-old chicks killed for commercial reasons;]			
(²) and/or	· [—	animal by-products from aquatic or terrestrial invertebrates other than species pathogenic to humans or animals;]			
( <sup>2</sup> ) and/or	· [—	animals and parts thereof of the zoological orders of Rodentia and Lagomorpha, except Category 1 material as referred to in Article 8(a)(iii), (iv) and (v) and Category 2 material as referred to in Article 9(a) to (g) of Regulation (EC) No 1069/2009;]			
(²) and/or	· [—	products derived from or generated by:			
		<ul> <li>aquatic animals, and parts of such animals, except sea mammals, which did not show any signs of disease communicable to humans or animals,</li> </ul>			
		<ul> <li>aquatic or terrestrial invertebrates other than species pathogenic to humans or animals,</li> </ul>			
		<ul> <li>animals and parts thereof of the zoological orders of Rodentia and Lagomorpha, except Category 1 material as referred to in Article 8(a)(iii), (iv) and (v) and Category 2 material as referred to in Article 9(a) to (g) of Regulation (EC) No 1069/2009;]</li> </ul>			
( <sup>2</sup> ) and/or	[—	animals and parts of animals, other than those referred to in Article 8 or Article 10 of Regulation (EC) No 1069/2009,			
		<ul> <li>that died other than by being slaughtered or killed for human consumption, including animals killed for disease control purposes;</li> </ul>			
		(ii) foetuses;			
		(iii) oocytes, embryos and semen which are not destined for breeding purposes; and			
		(iv) dead-in-shell poultry;]			
(²) and/or	· (—	animal by-products other than Category 1 material or Category 3 material;]			

	Intermediate products to be used for the manufacture of medicinal products, veterinary medicinal products, medical devices for medical and veterinary purposes, active implantable medical devices, in vitro diagnostics medical devices for medical and veterinary purposes,			
COUNTRY	laboratory reagents, and cosmetic products			
II. Health information	II.a. Certificate reference No II.b.			
DEVICES FOR MEDICAL AND VET DIAGNOSTIC MEDICAL DEVICE	R MEDICINAL PRODUCTS/VETERINARY MEDICINAL PRODUCTS/MEDICAL ERINARY PURPOSES/ACTIVE IMPLANTABLE MEDICAL DEVICES/IN VITRO ES FOR MEDICAL AND VETERINARY PURPOSES/LABORATORY ONLY' and it is not intended to be diverted at any stage within the Union for any			
(5) the consignment will be transported d that is:	rectly to the place of destination as indicated under point I.12 of this declaration,			
for medical and veterinary purpo medical and veterinary purpos	<ul> <li>an establishment or plant for the production of medicinal products, veterinary medicinal products, medical devices for medical and veterinary purposes, active implantable medical devices, in vitro diagnostic medical devices for medical and veterinary purposes, laboratory reagents or cosmetic products, which has been registered in accordance with Article 23 of Regulation (EC) No 1069/2009,</li> </ul>			
	has been approved in accordance with Article 24(1)(i) of Regulation (EC) No all only be dispatched to an establishment or plant referred to in the preceding			
Notes				
<ul> <li>Box reference I.19: use appropriate Harmo 05.07; 05.11; 12.12; 21.06; 30.01; 30.02; 3</li> </ul>	nised System (HS) code under the following headings: 02.06; 04.07; 04.08; 05.06; 1.01; 51.01, 51.02 or 15.05.00.			
- Box reference I.25: technical use: any use	other than for animal consumption.			
( <sup>1a</sup> ) OJ L 54, 26.2.2011, p. 1.				
<sup>1b</sup> ) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1), Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67), Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1) and Directive 98/79/EC of the European Parliament and the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ L 331, 7.12.1998, p. 1), Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (OJ L 262, 27.9.1976, p. 169), as appropriate.				
( <sup>2</sup> ) Delete as appropriate.				
The importer				
Name (in capital letters):	Address:			
Date:	Signature:			

# [<sup>F12</sup>CHAPTER 21

## Model declaration

Declaration by the importer of untreated wool and hair referred to in Article 25(2)(e) for import to the European Union]

COL	OUNTRY:					
	l.1.	Consignor Name	1.2. Certificate reference No 1.2.a.			
		Address	I.3. Central competent authority			
of dispatched consignment		Tel.	I.4. Local competent authority			
	1.5.	Consignee Name Address	1.6. Person responsible for the load in EU Name Address			
atched co		Country Tel.	Postcode Tel.			
ls of disp	1.7.	Country of origin ISO code I.8. Region of origin Code	1.9. Country of ISO code I.10. Region of Code destination			
Detai	I.11.	Place of origin	I.12. Place of destination			
Part I: Details		Name Approval number Address	Name Approval number Address			
		Country	Postal code / Region			
	I.13.	Place of loading Address	I.14. Date of departure			
	I.15.	Means of transport	I.16. Entry BIP in EU			
		Aeroplane Ship Railway wagon	Name Unit no			
		Road vehicle Other I Identification	I.17. No(s) of CITES			
	I.18.	Description of commodity	I.19. Commodity code (HS code)			
			I.20. Quantity			
	1.21.	Temperature of product Ambient	I.22. Number of packages			
	1.23.	Seal/Container No	I.24. Type of packaging			
	I.25. Commodities certified for:					
	1.26.	For transit through EU to third country	1.27. For import or admission into EU			
		Third country ISO code				
		Nature of commodity	Net weight			

	COUNTRY:			Wool and hair referred to in Article 25(2)(e) of Regulation (EU) No 142/2011				
	Ш.	Health information		II.a. Certificate reference No	II.b.			
	DE	CLARATION						
	I, the undersigned, declare that the untreated wool (1) and/or hair (1) is produced from animals other than those of the porcine							
(a) at least 21 days before the date of entry into the Union;								
Certifica		(b) in a third country or region thereof as listed in Part 1 of Annex II to Regulation (EU) No 206/2010 and authorised for imports into the Union of fresh meat of ruminants not subject to supplementary guarantees A and F mentioned therein; and						
Part II: Certification			to in point (b) free of foot-and-mouth o accordance with the basic general cri					
	No	Notes:						
	This declaration is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post and must be issued in at least one official language of the Member State through which the consignment first enters the Union and in at least one official language of the Member State of destination.							
	Pa	rt I:						
	-	- Box reference I.11 & I.12: Approval number: the registration number of the esatblishment or plant, which has been issued by the comptent authority.						
	-	- Box reference I.19: Use the appropriate Harmonised System (HS) code of the World Customs Organisation of the following headings: 5101 or 5102						
	-	- Box reference I.20: Quantity: indicate the total gross and net weight in kg						
	- Box reference I.28: Nature of commodity : Indicate wool and hair							
	Pa	Part II:						
	( <sup>1</sup> )	<sup>1</sup> ) Delete as appropriate.						
	(²)	) The signature must be in colour different to that of the printing.						
		The importer						
		Name (in capital letters):		Addr	ess:			
		Date:		Sign	ature:			
		Place:						

### ANNEX XVI

### **OFFICIAL CONTROLS**

### CHAPTER I

### OFFICIAL CONTROLS IN PROCESSING PLANTS

### Section 1

#### Supervision of the production

1. The competent authority shall supervise processing plants to ensure compliance with the requirements of Regulation (EC) No 1069/2009 and with this Regulation.

It shall, in particular:

- (a) check:
  - (i) the general conditions of hygiene of the premises, equipment and staff;
  - (ii) the efficacy of the own checks carried out by the operator of the processing plant, in accordance with Article 28 of Regulation (EC) No 1069/2009; such checks must include an examination of the results of those checks and if necessary, the taking of samples;
  - (iii) the effective implementation of the permanent written procedure based on the HACCP principles in accordance with Article 29(1) of Regulation (EC) No 1069/2009; such checks must include an examination of the results of this implementation and if necessary, the taking of samples;
  - (iv) the standards of the products after processing; the analyses and tests must be carried out in accordance with scientifically recognised methods, in particular, those laid down in Union legislation or, where no such methods are laid down in Union legislation, in accordance with recognised international standards or, in their absence, national standards; and
  - (v) the storage conditions;
- (b) take any samples required for laboratory tests; and
- (c) make any other checks it considers necessary to ensure compliance with Regulation (EC) No 1069/2009 and with this Regulation.
- 2. To allow it to carry out its responsibilities under point 1, the competent authority must have free access at all times to all parts of the processing plant and to records, commercial documents and health certificates.

### Section 2

#### Validation procedures

1. Prior to issuing an approval for a processing plant, as provided for in Article 44(1) of Regulation (EC) No 1069/2009, the competent authority must check that a validation

of the processing plant has been carried out by the operator in accordance with the following procedures and indicators:

- (a) a description of the process by a process flow diagram;
- (b) an identification of critical control points (CCPs) including the material process rate for continuous systems;
- (c) the compliance with the specific process requirements laid down by this Regulation; and
- (d) the achievement of the following requirements:
  - (i) particle size for batch-pressure and continuous processes, defined by the mincer hole or the anvil gap size;
  - (ii) temperature, pressure, processing time and, in the case of continuous processing systems, the material processing rate, as specified in points 2 and 3.
- 2. In the case of a batch pressure system:
- (a) the temperature must be monitored with a permanent thermocouple and it must be plotted against real time;
- (b) the pressure stage must be monitored with a permanent pressure gauge; pressure must be plotted against real time;
- (c) the processing time must be shown by time/temperature and time/pressure diagrams.

At least once a year the thermocouple and the pressure gauge must be calibrated.

- 3. In the case of a continuous pressure system:
- (a) the temperature and the pressure must be monitored with thermocouples, or an infrared temperature gun, and pressure gauges must be used at defined positions throughout the process system in such a way that temperature and pressure comply with the required conditions inside the whole continuous system or in a section of it; the temperature and pressure must be plotted against real time;
- (b) measurement of the minimum transit time inside the whole relevant part of the continuous system where the temperature and pressure comply with the required conditions, must be provided to the competent authorities, using insoluble markers, such as manganese dioxide, or a method which offers equivalent guarantees.

Accurate measurement and control of the material process rate is essential and must be measured during the validation test in relation to a CCP that can be continuously monitored such as:

- (i) feed screw revolutions per minute (rev./min.);
- (ii) the electric power (amps at given voltage);
- (iii) the evaporation/condensation rate; or
- (iv) the number of pump strokes per unit time.

All measuring and monitoring equipment must be calibrated at least once a year.

4. The competent authority must repeat the checks on the validation procedures when it considers it necessary, and in any case each time any significant alterations are made to the process, such as modifications of the machinery or changes of raw materials.

## CHAPTER II

#### LISTS OF REGISTERED AND APPROVED ESTABLISHMENTS, PLANTS AND OPERATORS

1. Access to lists of registered and approved establishments, plants and operators

In order to assist Member States in making up-to-date lists of registered and approved establishments, plants and operators available to other Member States and to the public, the Commission shall provide a website which shall contain links to the national websites provided by each Member State, as referred to in point 2(a).

- 2. Format for national websites
- (a) Each Member State shall provide the Commission with a linking address to a single national website containing the master list of all registered and approved establishments, plants and operators on its territory ('master list').
- (b) Each master list shall consist of one sheet and shall be completed in one or more official languages of the Union.
- 3. The layout, including the relevant information and codes, of master lists shall follow the technical specifications which are published by the Commission on its website.

### CHAPTER III

### SPECIFIC REQUIREMENTS FOR OFFICIAL CONTROLS

### Section 1

### **Official controls regarding marking of derived products**

The competent authority shall carry out a performance check of the monitoring and recording system referred to in point 2 of Chapter V of Annex VIII to this Regulation to ascertain compliance with this Regulation and may, where necessary, request the testing of additional samples in accordance with the method referred to in the second paragraph of the same point.

### Section 2

#### Official controls in low-capacity incineration plants

The competent authority shall inspect a low-capacity incineration plant for incineration of specified risk materials before approval, and at least once a year to monitor compliance with Regulation (EC) No 1069/2009 and with this Regulation.

#### Section 3

#### Official controls in remote areas

In the case of disposal of animal by-products in remote areas in accordance with Article 19(1) (b) of Regulation (EC) No 1069/2009, the competent authority shall monitor regularly the areas categorised as remote areas to ensure that those areas and the disposal operations are properly controlled.

#### Section 4

#### Official controls in registered farms for the feeding of fur animals

- 1. The competent authority shall take the necessary measures to control:
- (a) the appropriate composition, processing and use of the feed containing meat-and-bone meal or other products which have been processed in accordance with the processing methods set out in Chapter III of Annex IV and which are derived from the bodies or parts of bodies of animals of the same species;
- (b) that the animals are fed with the feed referred to in point (a), including:
  - (i) strict supervision of the health status of those animals; and
  - (ii) appropriate TSE surveillance involving regular sampling and laboratory examination for TSEs.
- 2. The samples referred to in point 1(b)(ii) shall include samples taken from animals showing neurological symptoms and from older breeding animals.

#### Section 5

#### Official controls regarding collection centres

- 1. The competent authority shall:
- (a) include collection centres into the list drawn up in accordance with Article 47(1) of Regulation (EC) No 1069/2009;
- (b) assign an official number to each collection centre; and
- (c) update the list of collection centres and make it available together with the list drawn up in accordance with Article 47(1) of Regulation (EC) No 1069/2009.
- 2. The competent authority shall carry out official controls at collection centres in order to verify compliance with this Regulation.

## [<sup>F1</sup>Section 6

# Official controls regarding the feeding of wild animals and certain zoo animals with Category 1 material

The competent authority shall monitor the health status of the farmed animals in the region where feeding is carried out as referred to in Sections 2, 3 and 4 of Chapter II of Annex VI

and shall carry out appropriate TSE surveillance involving regular sampling and laboratory examination for TSEs.

Those samples shall include samples taken from suspected animals and from older breeding animals.]

### Section 7

# Official controls regarding the application of certain organic fertilisers and soil improvers

The competent authority shall carry out controls along the entire chain of production and use of organic fertilisers and soil improvers subject to the restrictions referred to in Chapter II of Annex II.

Those controls shall include checks on the mixing with a component referred to in point 2 of Section 1 of Chapter II of Annex XI, and checks on the stocks of such products kept on farm and the records kept in accordance with Regulation (EC) No 1069/2009 and with this Regulation.

### Section 8

#### Official controls regarding approved photographic factories

The competent authority shall carry out documentary checks in approved photographic factories referred to in Table 3 of point 1 of Section 11 of Chapter II of Annex XIV on the channelling chain from the border inspection posts of first entry to the approved photographic factories for the purpose of reconciliation of the quantities of products imported, used and disposed of.

### Section 9

#### Official controls regarding certain imported rendered fats

The competent authority shall carry out documentary checks in registered establishments or plants receiving rendered fats which have been imported in accordance with Section 9 of Chapter II of Annex XIV on the channelling chain from the border inspection posts of first entry to the registered establishment or plant for the purpose of reconciliation of the quantities of products imported, used and disposed of.

## [<sup>F10</sup>Section 10

#### Standard format for applications for certain authorisations in intra-Union trade

Operators shall apply to the competent authority of the Member State of destination for the authorisation of the dispatch of animal by-products and derived products referred to in Article 48(1) of Regulation (EC) No 1069/2009 in accordance with the following format:]

	PAGE 1/2				
APPLICATION FOR THE AUTHORISATION OF THE DISPATCH OF ANIMAL					
BY-PRODUCTS AND DERIVED PRODUCTS TO ANOTHER MEMBER STATE (ARTICLE 48 OF REGULATION (EC) No 1069/2009)					
¢					
Name and address of place of origin	Approval or registration number, issued by (competent authority)				
Name and address of consignor	Approval or registration number, issued by (competent authority)				
Name and address of applicant	Approval or registration number, issued by (competent authority)				
Name and address of place of destination	Approval or registration number, issued by (competent authority)				
Animal by-products/derived products ( <sup>1</sup> )	Intended use (1)				
Category 1 material consisting of:	Disposal				
(nature of the material)	Processing				
	Combustion				
Category 2 material consisting of:	Application to land				
(nature of the material)	Transformation into biogas				
Meat-and-bone meal derived from Category 1 material	Composting				
Animal fat derived from Category 1 material	Petfood ( <sup>2</sup> )				
	Production of biodiesel				
Meat-and-bone meal derived from Category 2 material	For feeding to ( <sup>3</sup> ):				
Animal fat derived from Category 2 material					
	For the manufacture of the following derived products ( <sup>4</sup> ):				
Indicate the quantity of animal by-products/derived products (volume or mass) ( <sup>4</sup> ) ( <sup>5</sup> )					

# *Changes to legislation:* There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011. (See end of Document for details)

	PAGE 2/2				
(APPLICATION FOR THE AUTHORISATION OF THE DISPATCH OFANIMAL BY-PRODUCTS AND DERIVED PRODUCTS TO ANOTHER MEMBER STATE					
(ARTICLE 48 OF REGULATION (EC) No 1069/2009))					
In case of meat-and-bone meal and animal fat:	Species of origin:				
The materials have been processed according to the following method (°):					
I, the undersigned, declare that the above information is factually correct.					
(Signature: name, date, contact details: telephone, fax (if applicable), e-mail)					
Decision by the competent authority of the Member State of destination (7):					
The dispatch of the consignment is:					
refused.					
accepted.					
accepted subject to the application of pressure sterilisation (method 1) to the materials.					
accepted subject to the following conditions for the dispatch ( <sup>4</sup> ):					
This authorisation is valid until:					
(Date, stamp and signature of the competent authority)					

#### Notes:

Complete the document in BLOCK capitals.

(1) Tick as appropriate.

(\*) In the case of petfood produced with Category 1 material comprising animal by-products derived from animals which have been submitted to illegal treatment as defined in Article 1(2)(d) of Directive 96/22/EC or Article 2(b) of Directive 96/23/EC.

(3) Specify in accordance with Article 18 of Regulation (EC) No 1069/2009.

(4) Fill in, if appropriate.

(5) Specify.

(6) Specify one of the processing methods referred to in Chapter III of Annex IV to Regulation (EU) No 142/2011.

 $(^{7})$  For the competent authority: tick as appropriate.

(8) Insert date of expiration of authorisation.

### *<sup>F3</sup>Section 11*

#### Official controls regarding hydrolysis with subsequent disposal

The competent authority shall carry out controls at sites where hydrolysis with subsequent disposal is carried out in accordance with point B of Section 2 of Chapter V of Annex IX.

Such controls shall, for the purpose of reconciliation of the quantities of hydrolysed materials dispatched and disposed of, include documentary checks:

- (a) of the amount of materials which are hydrolysed at the site;
- (b) in the establishments or plants where the hydrolysed materials are disposed of.

Controls shall be carried out regularly on the basis of a risk assessment.

During the period of the first 12 months of operation, a control visit to a site, where a container for the hydrolysis is located, shall be carried out every time hydrolysed material is collected from the container.

Following the period of the first 12 months of operation, a control visit to such sites shall be carried out every time the container is emptied and checked for the absence of corrosion and leaking in accordance with point B(3)(j) of Section 2 of Chapter V of Annex IX.]

## [<sup>F7</sup>Section 12

# Official controls regarding approved plants for the combustion of animal fat and poultry manure as a fuel

The competent authority shall carry out documentary checks in approved plants for combustion of animal fat and poultry manure as a fuel referred to in Chapter V of Annex III in accordance with the procedures referred to in Article 6(7) and (8).]

- (1) [<sup>F9</sup>BS EN 12880:2000, Characterization of sludges. Determination of dry residue and water content. European Committee for Standardisation,]
- (2) [<sup>F9</sup>CEN EN 459-2:2002 method CEN/TC 51 Cement and building limes. European Committee for Standardisation,]
- (**3**) [<sup>F1</sup>OJ L 135, 30.5.1991, p. 40.]
- (4) CEN TC/102 Sterilisers for medical purposes EN 285:2006 + A2:2009 Sterilization Steam Sterilisers Large Sterilisers, reference published in OJ C 293, 2.12.2009, p. 39.
- (5) F<sub>0</sub> is the calculated killing effect on bacterial spores. An F<sub>0</sub> value of 3, 00 means that the coldest point in the product has been heated sufficiently to achieve the same killing effect as 121 °C (250 °F) in three minutes with instantaneous heating and chilling.
- (6) UHT = Ultra High Temperature treatment at 132 °C for at least one second.
- (7) HTST = High Temperature Short Time pasteurisation at 72 °C for at least 15 seconds or equivalent pasteurisation effect achieving a negative reaction to a phosphatase test.

#### **Textual Amendments**

- F1 Substituted by Commission Regulation (EU) No 294/2013 of 14 March 2013 amending and correcting Regulation (EU) No 142/2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (Text with EEA relevance).
- F9 Inserted by Commission Regulation (EU) No 749/2011 of 29 July 2011 amending Regulation (EU) No 142/2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (Text with EEA relevance).

## Status:

Point in time view as at 23/02/2015.

#### Changes to legislation:

There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011.